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Design and implementation of a second prototype of the intelligent alarm system in anesthesia

by
J.A. Nederstigt

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OF THE INTELLIGENT ALARM SYSTEM IN ANESTHESIA

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This report was submitted in partial fulfillment of the requirements for the degree of Master of Electrical Engineering at the Eindhoven University of Technology, The Netherlands.

The work was carried out from November 1988 until October 1989 at the Department of Anesthesiology, College of Medicine, University of Florida, Gainesville, Florida, under supervision of Professor J.E.W. Beneken, Ph.D., and J.J. van der Aa, M.E.E.

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SUMMARY

In today's operating room (OR), a number of monitors is connected to both patient and equipment. Each individual monitor is equipped with its own, usually rather unspecific, alarms. Therefore, there is a clear need for an integrated alarm system that, by combining data from all monitors, generates useful and intelligent alarm messages about possible abnormalities occurring in patient and/or equipment.

A first prototype of such a system, combining data from three different monitors to detect mechanical malfunctions in the breathing circuit, was tested on an anesthesia simulator and in the OR. During tests with the simulator, the system identified 88% of the introduced malfunctions correctly within 30 seconds. No false alarms were recorded in the OR, although the signals were often disturbed.

A second prototype was designed to adapt automatically to adjustments in one or more of the control settings on the anesthesia machine or the anesthesia ventilator during surgery. Furthermore, a user-friendly interface screen was designed for this system. During tests on the simulator, 95.5% of the malfunctions was detected correctly. The system could keep up with high pediatric respiratory rates.

After some additional refinements and improvements, the system can be the platform for the development of a completely integrated intelligent alarm system for patient as well as equipment during anesthesia.

SAMENVATTING

In de moderne operatiekamer (OK) wordt zowel de toestand van de patient als het functioneren van de anesthesiemachine continu in de gaten gehouden met behulp van een steeds groeiend aantal meetapparaten. Elke monitor is uitgerust met zijn eigen, niet specifieke, alarms. Daardoor is er een duidelijke behoefte ontstaan aan een geïntegreerd alarm systeem dat, door het combineren van data van verschillende monitoren, in staat is bruikbare en intelligente alarmboodschappen te genereren wanneer er iets misgaat.

Een eerste prototype van zo'n systeem, dat data van drie verschillende meetapparaten gebruikt om mechanische defecten in het beademingscircuit op te sporen, is getest met behulp van een anesthesiesimulator en in de OK. Tijdens de testen met de simulator was het systeem in staat om 88% van de geïntroduceerde defecten correct te identificeren binnen 30 seconden. In de OK werden geen valse alarms geregistreerd, ondanks het feit dat de signalen vaak gestoord werden.

Een tweede prototype is ontworpen dat in staat is zich automatisch aan te passen wanneer instelwaarden op de anesthesiemachine en/of de ventilator tijdens de operatie worden veranderd. Verder is een gebruikersvriendelijk, gemakkelijk te interpreteren display ontworpen voor dit systeem. Tijdens testen met de simulator kon dit systeem 95.5% van de defecten correct opsporen. Tevens leverden de hoge beademingsfrequenties die vaak bij jonge kinderen worden gebruikt geen problemen op.

Met enkele verbeteringen en uitbreidingen kan het systeem als basis dienen voor de ontwikkeling van een compleet geïntegreerd, intelligent alarm systeem voor de combinatie patient-anesthesiemachine.

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Table of Abbreviations

AD	=	analog to digital
BOVI	=	electrocautery
CO ₂	=	carbon dioxide
ECG	=	electro-cardiogram
E.T. tube	=	endotracheal tube
FGF	=	fresh gas flow
IASA	=	intelligent alarm system in anesthesia
I:E	=	ratio of inspiration to expiration time
I/O	=	input/output
N ₂ O	=	nitrous oxide
O ₂	=	oxygen
OR	=	operating room
PEEP	=	positive end expiratory pressure
RR	=	respiratory rate
V _T	=	tidal volume

Table of Medical Terms

abdomen	:	belly
analgesia	:	insensitivity to pain
anesthesia machine	:	machine preparing the gas mixture delivered to the patient during general anesthesia
artificial nose	:	device inserted into the breathing circuit to moisten the inhaled gases
breathing circuit	:	network of hoses and valves connecting the patient to the anesthesia machine
electrocautery	:	the process of cutting the patient's skin by means of a high frequency, high power electrical signal
endotracheal tube	:	tube inserted into the patient's airway during general anesthesia, connects the patient to the breathing circuit
enflurane	:	anesthetic agent, added to the inhaled gas mixture
halothane	:	see enflurane
hypoxia	:	situation in which the oxygen saturation of the patient's blood is too low
isoflurane	:	see enflurane
narcosis	:	unconsciousness
scavenging system	:	system that removes excess anesthetic gases from the breathing circuit
ventilator	:	device that forces fresh gas into the patient's lungs via the breathing circuit

INTRODUCTION

During surgery the patient is under anesthesia: unconscious and insensitive to pain. The anesthesiologist maintains the patient's vital organ function during anesthesia. The clinician gets important information about the patient's status from several monitors connected to both patient and equipment. However, the number of monitors increases steadily in today's operating room (OR), making the situation more and more complex. Each monitor is equipped with its own alarms, generating a sound or displaying a message whenever a measured quantity exceeds its user-defined threshold. During a number of situations, many monitors sound an alarm simultaneously, making it very difficult for the clinician to diagnose the situation and correct an emerging problem.

A few years ago, the Intelligent Alarms Project was started as a joint venture between the University of Florida, Gainesville, U.S.A., and the Eindhoven University of Technology, Eindhoven, the Netherlands, with the intention to develop a working prototype of an integrated alarm system. This system should combine several signals in order to come up with intelligent alarm messages whenever an abnormality is detected during the course of anesthesia. In 1988, Van Oostrom [1] implemented a first version that processes three signals measured in the anesthesia breathing circuit, transforms the signals into symbolic "feature" data and evaluates and combines these symbolic data using a rule based expert system. From this first prototype, a refined system was developed and tested. The system concentrates on mechanical malfunctions in the breathing circuit.

After an introduction to anesthesia (chapter 1) and current alarm strategies (chapter 2), the configuration of the final version of this first prototype is described in chapter 3. The results of extensive testing procedures are given in chapter 4.

The second goal of this thesis research project is to design and implement a second prototype Intelligent Alarm System, able to adapt automatically whenever the clinician changes control settings on the anesthesia machine or ventilator (the

first prototype is not able to do this). In chapter 5 the concepts and algorithms used in this second prototype are described, while in chapter 6 the first test results of this system are presented.

Funding for the research was provided by Ohmeda Medical Products, Madison WI, U.S.A., a company manufacturing anesthesia equipment.

CHAPTER 1: A SHORT INTRODUCTION TO ANESTHESIA

Before addressing the issues of monitoring and alarms during anesthetic procedures a brief introduction to anesthesiology is given in this chapter.

During surgery the patient is in a state of narcosis (unconsciousness), muscle relaxation and analgesia (insensitivity to pain), usually referred to as general anesthesia [2]. This condition is induced by an anesthesiologist who administers a combination of intravenous and inhalation drugs to the patient. The task of the anesthesiologist is to maintain the patient's vital organ function while adequate levels of anesthesia are sustained. In order to facilitate this task the patient is connected to an anesthesia machine via a breathing circuit and to all kinds of monitoring equipment. In the next paragraphs a short functional description of the anesthesia system and the most common monitoring equipment is given.

1.1 The Anesthesia System

An important part of the anesthesia system is the anesthesia machine. It helps the anesthesiologist by preparing a gas mixture with precisely known but variable composition which is administered to the patient. In the United States the gas combination most frequently used consists of oxygen (O_2), nitrous oxide (N_2O) and an anesthetic agent (halothane, isoflurane, or enflurane). The anesthesiologist can control the relative volume of each of these composites. He delivers the gas mixture to the patient by manually squeezing a "breathing bag" or by using a mechanical ventilator usually mounted on the anesthesia machine.

The anesthetic system is generally divided into 5 major parts [1]:

1. High pressure system,
2. Low pressure system,
3. Breathing circuit,
4. Ventilator system,
5. Scavenging system.

A schematic of the entire anesthesia system is given in figure 1.1.

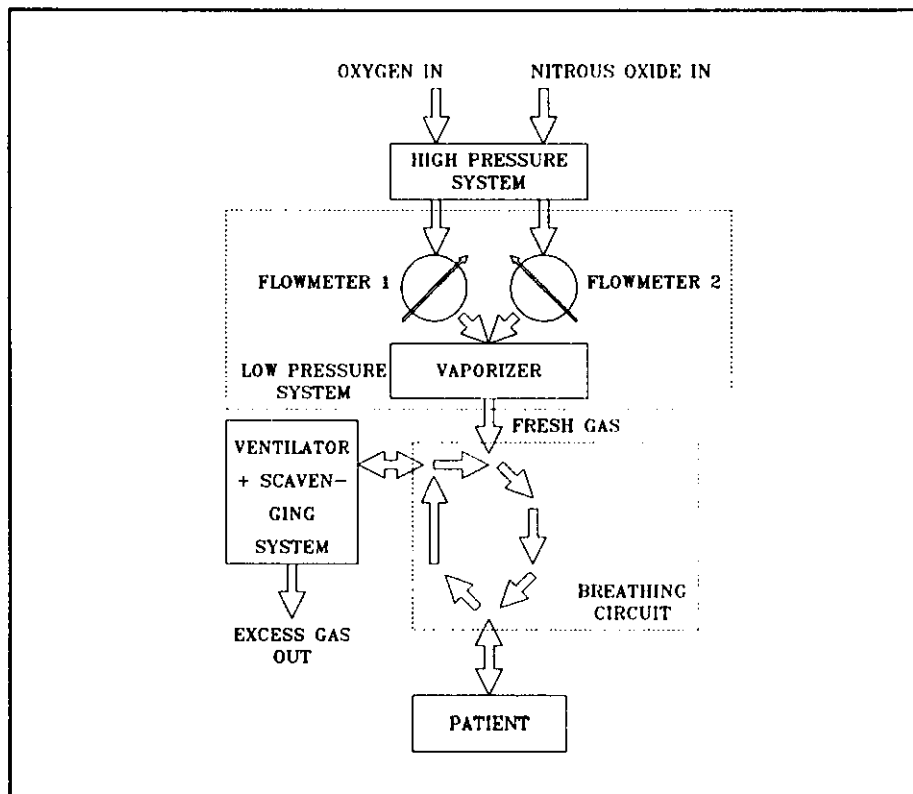


Figure 1.1: Schematic of the anesthesia system. The arrows indicate gas flows.

The 5 parts of the anesthesia system from figure 1.1 can be described as follows:

1. The high pressure system regulates the gases coming from the hospital pipeline system (O_2 , N_2O , and usually air) or, in case of pipeline failure, from cylinders mounted on the back of the anesthesia machine. The highly pressurized gases are converted to low pressure by a network of pipes, valves and regulators inside the anesthesia machine [3] before they enter the low pressure system.

2. The low pressure system contains separate flowmeters that are calibrated for either O_2 , N_2O or air. With control knobs the anesthesiologist can adjust the gas flow for each of the components. Upon exiting the flow meters the gas

components are mixed and driven through a vaporizer, in which a controllable volume of anesthetic agent is added to the mixture. After passing the vaporizer the gas mixture leaves the anesthesia machine at the fresh gas outlet and enters the breathing circuit.

3. The breathing circuit shown in figure 1.1 is the circle breathing circuit, in which carbon dioxide (CO_2) is removed from the exhaled gas mixture by a CO_2 absorber. Most of the times the CO_2 absorber is placed in between the ventilator and the fresh gas inlet. In this way exhaled gases can be reused so that as little gas and anesthetic agent as possible is lost to the scavenging system.

The circle system is the most common breathing circuit used in the United States today, and is the main focus of our research. Other breathing circuits include the Bain and Mapleson systems [3] in which no rebreathing of anesthetic gases takes place. These circuits are not considered in our research.

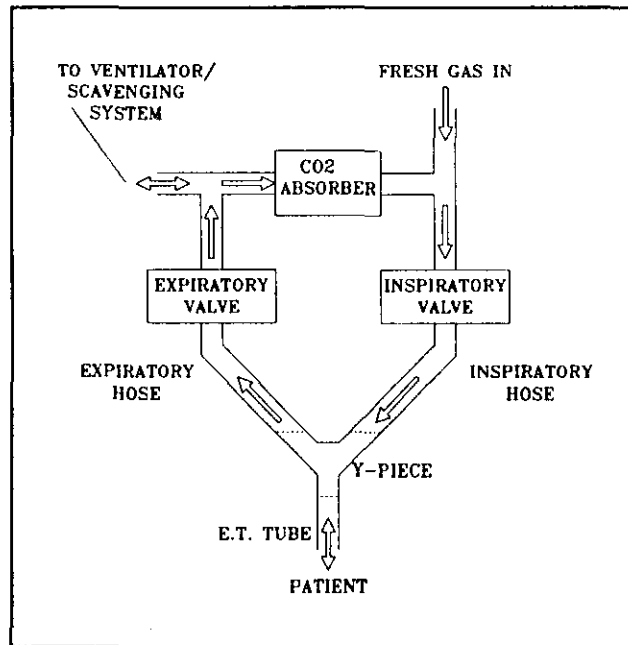


Figure 1.2: Detailed schematic of the circle breathing circuit. The arrows indicate gas flows.

A detailed schematic of the circle breathing circuit is given in figure 1.2. Important components include the inspiratory and expiratory hoses, two unidirectional valves, the CO₂ absorber and the endotracheal (E.T.) tube. All these parts together compose a system through which the patient is ventilated. The unidirectional valves (one is placed in the inspiratory, one in the expiratory hose) accomplish that gas inhalation and gas expiration take place through different hoses. In this way the expired (O₂ poor, CO₂ rich) gases cannot be reinspired at the next inhalation without having passed through the CO₂ absorber and along the fresh gas inlet. The E.T. tube is placed into the patient's airway by the anesthesiologist at the beginning of general anesthesia. The tube is connected with a "Y-piece" to the inspiratory and expiratory hoses. At the fresh gas inlet new O₂ rich gas from the anesthesia machine is mixed with the gas coming from the CO₂ absorber. This mixture is delivered to the patient [1,2,3].

4. The mechanical ventilator is the driving force behind the breathing system. It is used to move gas into the patient's lungs. Usually this is accomplished by periodically applying a positive pressure to a bellows connected to the airway, forcing the gas mixture through the inspiratory hose and the E.T. tube into the patient's lungs. When the lungs are filled to a suitable level, the positive pressure is removed. In this way the lungs can empty passively through the expiratory hose into the ventilator bellows. This process is repeated continuously.

The two types of mechanical ventilators commonly used in the United States are the constant flow generator and the constant pressure generator [4]. The constant flow generator delivers, as its name states, a constant but adjustable inspiratory gas flow to the patient whereas the constant pressure generator maintains a constant airway pressure during inspiration.

On the ventilator the anesthesiologist can make changes to adjust for type of operation, demographic patient data or specific patient conditions [1,4]. Adjustments can be made for tidal volume (V_T), respiratory rate (RR) and inspiratory to expiratory ratio (I:E). V_T is the gas volume delivered to the patient

during one breath, RR the number of respirations in one minute and I:E the ratio of inspiration to expiration time. Depending on the type of ventilator used, the fourth important setting is either the inspiratory flow (F_I , constant flow generator) or the inspiratory pressure (P_I , constant pressure generator).

The anesthesiologist can also switch to a breathing bag with which he can manually ventilate the patient. This is often used during emergency or during critical phases in anesthesia like intubation (entering the E.T. tube at the beginning) and extubation (taking out the E.T. tube thereby allowing the patient to breathe by himself after surgery).

5. The scavenging system removes excess gases from the breathing circuit. At the end of expiration a valve to the scavenging system opens, thereby allowing gas to leave the circuit. The scavenging system removes the excess gas from the operating room (OR) to prevent pollution of the clean OR air with anesthetic gases.

1.2 The Most Important Monitoring Equipment

During surgery a variety of monitors is connected to the patient while other measuring devices are inserted into the breathing system. This gives the anesthesiologist the ability to discover changes in the state of the patient or malfunctioning equipment as early as possible so that corrective action can be taken in time. A standard for minimal monitoring defined by the American Society of Anesthesiologists (ASA) in 1986 [5] requires that at least the patient's oxygenation, ventilation, circulation and temperature are monitored continuously.

In most cases the oxygen level of the inspired gas is measured with an O_2 analyzer placed in the breathing circuit near the fresh gas inlet.

Oxygenation of blood is usually measured with a pulse oximeter. This monitor uses differences in light absorption characteristics between hemoglobin and oxyhemoglobin to calculate the oxygen saturation of the blood.

The ventilation of the patient is typically measured with a capnograph. This device monitors the partial pressure of CO₂ in the gas mixture. The signal contains a variety of information about the patient and equipment statuses [6]. Most of the times the CO₂ content of the gas is measured at the Y-piece of the breathing circuit. Other common monitors that help the anesthesiologist evaluate the patient's ventilation are an airway pressure monitor (usually placed near the inspiratory one way valve) and a tidal volume or flow monitor in the expiratory limb of the breathing circuit [2].

In order to provide the anesthesiologist with some information about the patient's blood circulation two more variables are measured. The first signal, the electro-cardiogram (ECG), gives information about the electrical activity of the heart. The ECG is measured with three or more electrodes attached to the patient's chest. The second variable is the blood pressure. Blood pressure is measured continuously, usually noninvasively with an inflatable cuff. Sometimes, when the anesthesiologist wants to see a real time waveform, blood pressure is measured invasively with an arterial catheter.

Other variables monitored are temperature (typically measured with a thermocouple or thermistor based sensor) and the degree of muscle relaxation [2].

Despite this abundance of mechanical and electrical devices available to help the anesthesiologist, his own eyes, ears and sense of feeling are still the most important "monitors" available [2,7]. Thus, the alarm system described in this thesis should be considered as an attempt to provide the anesthesiologist with valuable extra information when time, an extremely important factor in emergency situations, is limited. It is certainly not an attempt to replace the anesthesiologist.

CHAPTER 2: ALARM STRATEGIES IN ANESTHESIA

Before describing our approach to design an "intelligent" integrated alarm system we review the work that already has been done in this area. In the next paragraphs an overview of the literature of the last decennium about alarms and integrated alarm systems in anesthesia is presented. A brief introduction to our strategy is given at the end of this chapter.

2.1 Current State of Alarm Technology

The purpose of alarms during anesthesia is to get the clinician's attention whenever a potential hazard is detected regarding the patient or the anesthesia equipment. For this purpose the monitors used during anesthesia are equipped with their own alarm limits. Currently, the available alarm technology relies on the "threshold-check". For each variable measured by a particular monitor, the clinician has to define what he considers the "normal" band before the start of anesthesia. This means that an alarm message will be generated when a variable exceeds either its upper or its lower limit. Usually the alarm is a tone of a certain frequency, sometimes combined with a text message on the monitor's display. When, for example, one only considers a blood pressure monitor, this strategy will certainly be appropriate. An alarm message is generated whenever e.g. the systolic blood pressure exceeds its set upper limit. In this case, the audio alarm will be specific and easy to interpret for the anesthesiologist.

However, the monitoring situation in today's operating room (OR) is more complicated. In paragraph 1.2 the minimal array of monitors used during anesthesia was briefly described. Each of these monitors has its own alarms, independent of all the others. Considering the fact that an alarm is usually accompanied by all sorts of other alarms some of the problems of the current strategy already become clear.

In an emergency situation, when many measured variables can exceed their set limits, the clinician's first reaction will be to silence the abundance of audio alarms. In these situations it is often very difficult for the anesthesiologist to diagnose the problem because the alarms are not specific and do not point out possible causes. Other problems that can be identified are [2]:

- It becomes increasingly impractical for the clinician to set all the thresholds for all the variables manually.
- The alarms do not give an early indication when the situation is slowly deteriorating without variables exceeding thresholds.
- There is no priority scheme for alarms coming from different monitors. All triggered alarms will ring the bell simultaneously.
- It is very difficult for a single variable monitor to detect the difference between a potentially hazardous situation and a threshold crossing triggered by a motion or other interference. This is the well-known artifact detection problem [9].

For all these reasons research efforts in the last few years have focused on how to generate helpful and specific alarms. Recent publications point out that multivariable analysis and integration is needed in order to come to more "intelligent" alarm messages. A brief survey of recently proposed alarm strategies, their problems, and examples of implemented and tested (prototype) systems is presented in the next paragraph.

2.2 Survey of Modern Alarm Strategies

The first attempt to compile a survey of research activities regarding alarm strategies and implementations other than the threshold-check was performed by Gravenstein et al. in 1987[8]. In this survey, Philip, Fukui, and Beneken propose three different approaches to sophisticated and useful alarms in patient monitoring.

Philip [10] defines the patient's state as the set of variables that must be known to manage the patient. In a first approximation he looks at only two possible patient states: the "correct state" and the "incorrect state". For the detection of abnormalities, a change detection scheme is used for all the monitored variables. Whenever a change is detected the patient will enter the "incorrect state". At the same time the dimension of the state vector changes from 1 (fault or no fault) to 4 (four different fault categories are distinguished) and an alarm message is generated. The algorithm determines whether the abnormality occurred in circulation, anesthesia, respiration, or metabolism (the 4 subsystems). The state dimension increases with growing severity of the situation. Circulation, for example, can be subdivided into medium (blood), conduits (blood vessels), and pump (heart). The advantage of this system is that the clinician only needs to observe a minimum number of variables during stable situations. A disadvantage, however, is the fact that the complexity of the system increases rapidly with a growing number of states.

Fukui [11] uses an approach borrowed from Artificial Intelligence (AI). A number of patient variables, including blood pressure, ECG, and temperature are continuously sampled and translated into one of three symbolic values. By comparing them to certain predefined thresholds each variable gets assigned a value "high", "low" or "just right". Pattern recognition techniques are used to identify abnormalities in the patient system. Fukui has implemented this algorithm together with a graphical display on which, among others, the blood pressure trend is displayed. Furthermore a sad or happy cartoon face gives an immediate and easy to interpret indication about the patient's condition.

Beneken et al. [12] use systems engineering principles in their approach. They consider the measured output quantities as a function of input variables, actual outputs, a noise component, and time. They use a patient model together with a library of fault models (each possible fault will have a certain unique effect on the measured output quantities). The algorithm reduces each measured variable to a three-digit number, which indicates the static, dynamic and stochastic

properties of the respective variable. Each fault model is stored as a set of these three-digit numbers. At any moment the algorithm can decide whether the patient is OK, and, if not, which is the most probable "fault".

Recently Philip [13] and Fukui [14] published an update on their ongoing research regarding their alarm algorithms mentioned before. Also, Beneken et al. [15] looked at alarms and their limits, on which issue we will come back in later chapters.

Apart from the Fukui system very few implemented integrated alarm systems are described in the literature. Most of them are outlined in the next paragraph.

2.2.1 Overview of Implemented Integrated Systems

One of the best structured alarm systems that is already commercially available is implemented in the Narkomed II anesthesia machine manufactured by North American Dräger. It is described by Schreiber et al. [16]. The system uses several sensors distributed over anesthesia machine, breathing circuit and patient, together with a centralized display. In this way the time the clinician needs to identify and correct a problem is minimized. A priority scheme is used to divide the alarm messages into warning, caution and advisory messages. Although the alarms are still threshold-based and no multivariable analysis is performed this is a first step toward smarter alarm systems.

Another implementation, although only on a prototype basis, is the Data Acquisition and Display System (DADS), developed at the Eindhoven University of Technology and described by Meijler [17]. This system incorporates a centralized display, automatic record keeping capabilities, and a threshold and trend detection scheme. The problem of many superfluous alarms is not solved however, basically because no multivariable analysis is performed.

A ventilator alarm system for use at the NASA Space Station, developed at the University of Utah by Brunner et al. [18], already incorporates some

"intelligence". A large number of transducers is placed at different sites of the breathing circuit and ventilator in order to identify several malfunctions during mechanical ventilation. Specific alarm messages can be generated by combining the signals coming from the different monitors via "if-then-else" rules. Early results indicate 98% correct identification of mechanical faults. The large number of sensors prevents the system from being commercially attractive at this moment.

Furthermore, an implementation of a "breathing gas interruption" monitor for use in the breathing circuit during mechanical ventilation is described by McEwen et al. [19,20]. This monitor can detect different hazardous situations in the breathing circuit by measuring only the pressure waveform. The waveform is compared to a learned "correct" waveform and when differences are detected an alarm message is generated. The alarms are not specific however, and no multisignal analysis is performed.

Other papers present only general conceptional or philosophical descriptions of system integration and use of computers for alarms in anesthesia [21,22,23].

2.3 The Gainesville Approach

As demonstrated in the beginning of this chapter there is a clear need for a system that is able to detect and identify abnormalities in the patient-machine combination during anesthesia. This has to be done in real time, by combining and evaluating several signals, derived variables and other patient data. The Intelligent Alarms System in Anesthesia (IASA) project started a few years ago at the University of Florida in Gainesville and the Eindhoven University of Technology with the intention to develop a working prototype of such a system. In this paragraph the general method is explained briefly before an extensive description of the first prototype configuration is presented in the next chapter.

The process the anesthesiologist goes through when he tries to locate and identify a problem during anesthesia can be divided into several phases. This

subsequent checking of different parts of the patient-equipment combination is schematically pictured in figure 2.1.

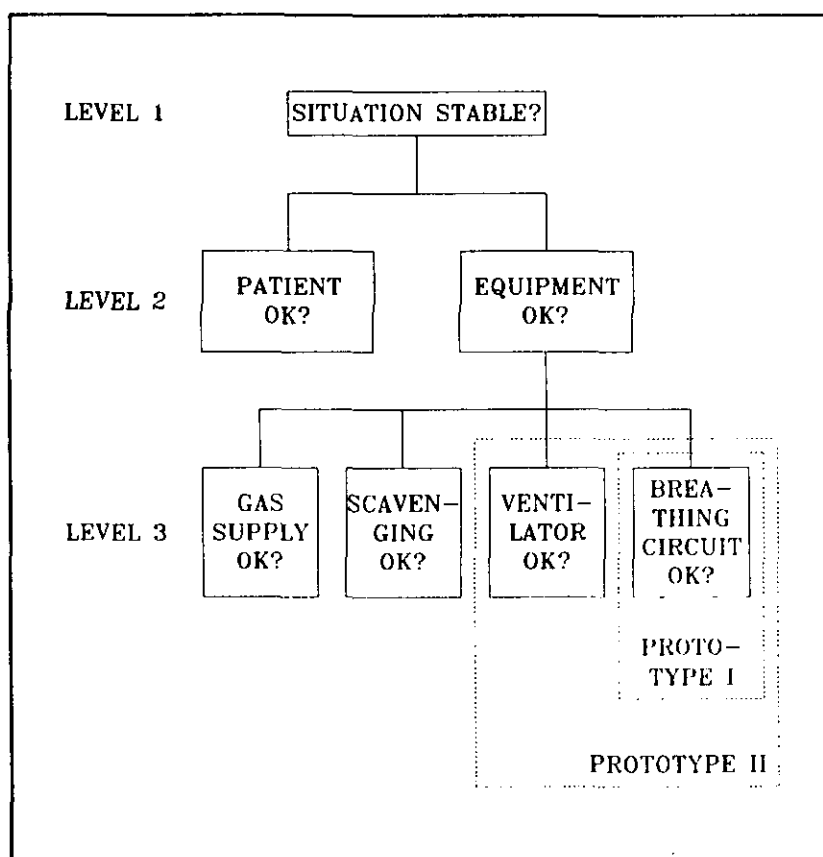


Figure 2.1: Schematic of the decision process of the anesthesiologist.

The final goal is to design a system that can give intelligent messages about abnormalities occurring in the patient as well as in the equipment. Because of the enormous complexity of especially the patient "system" (many factors influence the situation of the patient during anesthesia) we choose to start cautiously. The first prototype incorporates an alarm scheme that detects mechanical malfunctions in the breathing circuit during mechanical ventilation. This is performed by measuring and combining a carefully chosen set of signals in or close to the circle breathing circuit.

The goal for the second version is to incorporate ventilator related malfunctions in the alarm system. The target parts of prototypes I and II are illustrated in figure 2.1. The design and testing of these first two prototypes are described in the next chapters.

Once proven, these designs will be the platform to incorporate other patient variables and signals to come to a truly integrated alarm scheme.

CHAPTER 3: IASA: THE FIRST PROTOTYPE

The goal for the first prototype is the automated detection of the malfunctions that can occur in the circle breathing circuit during mechanical ventilation in the operating room (OR). In this chapter a detailed description of the software and hardware that composes this prototype alarm system is presented.

3.1 The Data Flow through the System

Before we look in more detail into the configuration of the system, a schematic of the data acquisition, signal processing, feature extraction and rule evaluation performed before an alarm message appears on the screen is pictured in figure 3.1. This design was proposed and first implemented by Van Oostrom [1] although the implementation of the signal processing part was already performed earlier by Bastings [24].

The system first processes three real time signals measured in the breathing circle: partial pressure of carbon dioxide (CO_2) at the Y-piece, airway pressure close to the inspiratory valve and airway flow through the expiratory valve. The signals are transformed into symbolic "feature" values and subsequently fed into a real time expert system at the end of each breath period (later on in this chapter we will define "breath period" and "feature"). Signals and signal features are chosen so that each fault that can occur in the breathing circuit will be reflected as a change in the set of symbolic data. The expert system evaluates and combines the feature data derived from the different signals, looks for changes in this data set, reaches a conclusion about the status of the breathing circle ("OK" or "ALARM"), and gives an "intelligent" indication about mechanical malfunctions that have occurred, together with their most probable site.

The signal processing, feature extraction and expert system approaches are described in detail in the following paragraphs.

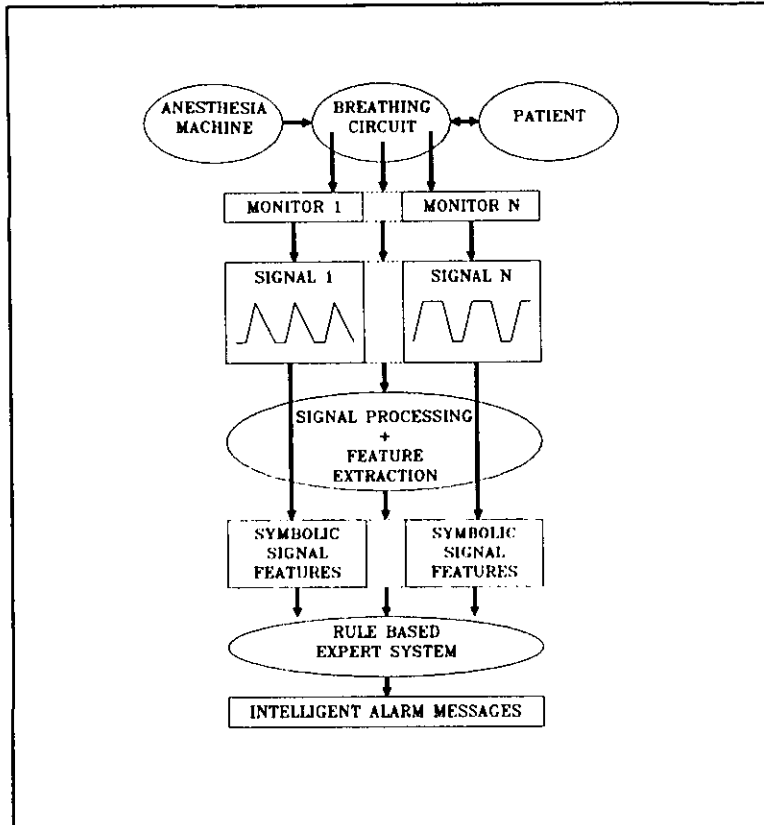


Figure 3.1: Data flow in prototype 1 of the Intelligent Alarm System.

3.2 Signals and Signal Processing

Van Oostrom [1] defines a list of malfunctions that can occur in the circle system and thus need to be detected by the alarm program. This list includes leaks at different sites, obstruction of the various hoses, disconnections, unidirectional valves that are stuck in the "open" position (due to moisture in the gas mixture), and exhaustion of the CO₂ absorber (the absorber can no longer remove CO₂ from the exhaled gas mixture).

Because the system needs to be clinically usable, it was decided to use only signals that are routinely measured in the breathing circuit during anesthesia. Furthermore, the number of sensors should be kept to a minimum in order not

to make the system more complicated than necessary. The set of signals chosen for prototype I consists, as mentioned in § 3.1, of the partial CO₂ pressure measured at the Y-piece of the breathing circuit, the airway pressure measured downstream (at the patient side) of the inspiratory unidirectional valve and the airway flow measured upstream (at the patient side) of the expiratory unidirectional valve (see also figure 1.2). This is the most common way of placing the sensors in today's clinical practice.

3.2.1 From Monitors to Sampled Signal Waveforms

Standard monitors manufactured by Ohmeda, Madison, WI, are used to obtain the waveforms. The Ohmeda 5200 CO₂ Monitor and the Ohmeda 5500 Airway Pressure Monitor provide analog outputs for the respective signals. The analog signals are fed to an analog to digital (AD) board inside an IBM AT compatible computer. With the AD-board sampled versions of the signals are produced. The samples serve as input to the signal processing software. Van Oostrom [1] describes how a real time flow signal is created by counting pulses generated by the Ohmeda 5410 Volume Monitor. Tests showed that a sampling frequency of 20 Hz is enough to calculate all signal features even at the highest respiratory rates (sometimes an RR of up to 30 breaths/min is used in pediatric or neonatal anesthesia).

A typical example of the three real time waveforms in a no-malfunction situation during mechanical ventilation of an adult patient is given in figure 3.2. During patient inspiration the pressure signal will go up linearly due to the constant flow the ventilator forces into the lungs. There is no flow in the expiratory limb of the circuit during inspiration. When the positive pressure from the ventilator is removed, the expiratory valve opens and the flow through the expiratory limb suddenly starts. This marks the start of patient expiration (see figure 3.2). At this moment CO₂ rich gas from the lungs starts passing the CO₂ sensor.

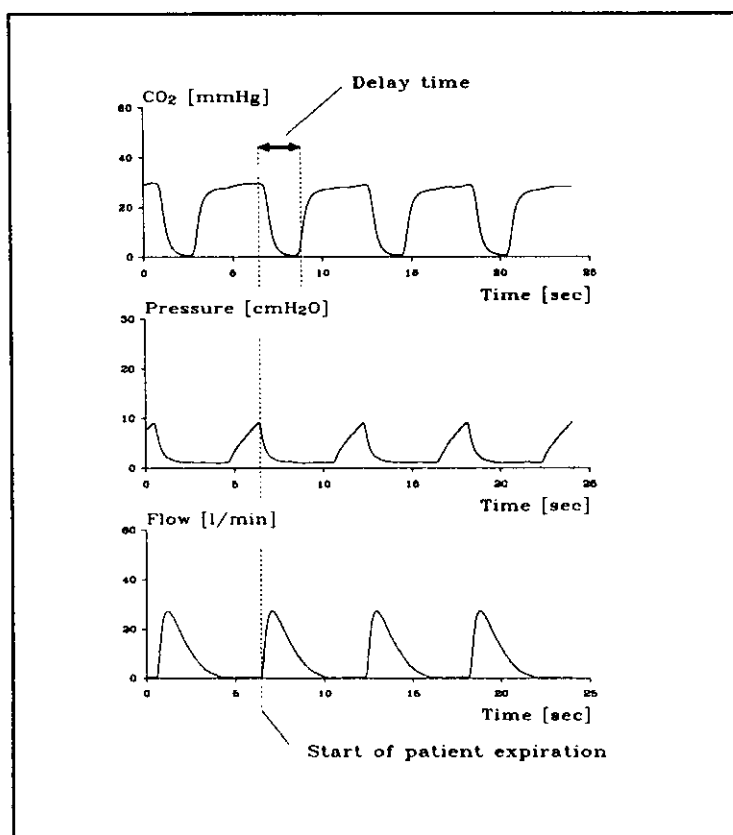


Figure 3.2: Example of 3 real time waveforms in an adult patient.

Since the lungs empty passively the flow and pressure signals show an exponential down slope (much like the discharging of a capacitor via a resistance), whereas the CO₂ signal increases quickly to an end expiratory "plateau" value. This value is approximately equal to the alveolar CO₂ concentration. With another inspiration, the patient will inhale fresh gas without CO₂ and thus the signal will go down to zero.

Due to the fact that the CO₂ monitor removes gas from the Y-piece via a sampling line, a delay is observed in this signal compared to the flow and pressure recordings. As can be seen from figure 3.2, gas transport from the Y-piece to the monitor takes approximately 2.5 seconds.

3.2.2 From Signals to Signal Features

For all three signals a breath detection and feature extraction algorithm is implemented that divides one (breath-) period of each signal into several "states". To explain the concepts of these algorithms we take the pressure signal as an example. In figure 3.3 the signal is pictured together with some help variables.

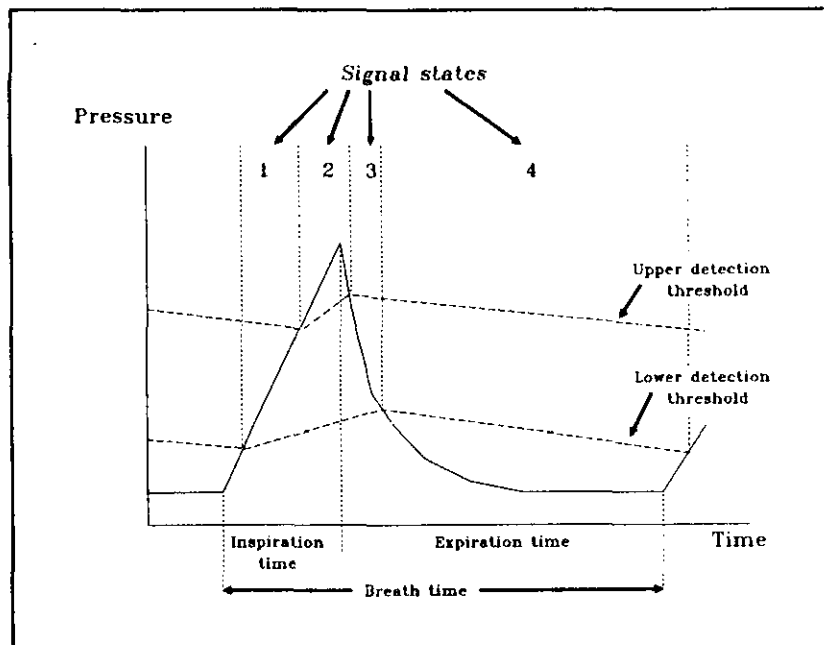


Figure 3.3: The pressure signal divided into several states.

The pressure signal is divided into 1) a linear inspiratory up slope, 2) a "maximum pressure" state, 3) an exponential expiratory down slope, and 4) a low end-expiratory "plateau". The algorithm uses adaptive upper and lower threshold values (see figure 3.3) to detect when a signal switches from one state to another [24]. For example, when the pressure signal crosses the lower threshold in the upper direction and the signal is currently in state 4 a switch from state 4 to state 1 will be performed. After every sample the algorithm first checks in which state the signal was, and then whether a state transition is detected. Depending on the new state, one or more variables that characterize the signal are updated

thereafter. For the pressure signal, the variable to be updated in state 1 is the pressure derivative or slope value (P_{slope}). In state 2 this is the maximum pressure (P_{max}), whereas the time constant of the down stroke (T_p) has to be estimated in state 3. Finally, in state 4 the algorithm looks for the minimum pressure (P_{min}). Other variables have to do with the timing and include inspiration time, expiration time and breath time. The theoretical value of these variables is indicated in figure 3.3. The inspiration time is estimated by adding the time periods of state 1 and 2, the estimated expiration time is the sum of the state 3 and state 4 time, breath time is the sum of both.

For the pressure signal, the transition from state 2 to state 3 is considered the start of a new breath period. For the flow signal a breath period starts with the detection of the "jump" in expiratory flow which ends the "zero-flow-period", whereas a new breath period for the CO_2 signal starts at the beginning of the up slope (see figure 3.2). This means that breath detection is performed at the start of patient expiration for every signal.

Thus, as soon as a new breath has been detected on every signal a complete set of numerical "features" representing one breath period of all signals is available. These features are used in the fault detection scheme. For the CO_2 signal the features include the inspired CO_2 level ($P_{i\text{CO}_2}$), the end-tidal CO_2 level ($P_{et\text{CO}_2}$), the values of the (linear) expiratory up slope and inspiratory down slope and the "plateau" time. The flow features are, next to timing variables, maximum flow (F_{max}), minimum flow (F_{min}), the time constant of the expiratory down stroke (T_F) and tidal volume (V_T). The latter variable is calculated by integrating the positive part of the flow curve during one breath period.

Van Oostrom [1] describes the algorithms used in the initial implementation for calculating maximum and minimum values, slopes and time constants. However, the time constant and slope algorithms have been updated to speed up the signal processing.

The derivative of the pressure waveform is updated and filtered after each incoming sample. The value of the filtered derivative at the moment the

algorithm detects a transition from state 1 to state 2 (see figure 3.3) equals P_{slope} . The results of this method turned out to be reliable and stable and were practically the same as the slope values acquired with the old least squares algorithm, whereas the speed of the new method is considerably higher.

In the following the technique used for estimating the time constant of the exponential down stroke in the pressure and flow signals is explained.

3.2.2.1 How to Estimate the Time Constant

We assume that the analog pressure signal $y(t)$ enters state 3 (see figure 3.3) at $t = 0$ sec. and exits this state at $t = T_{\text{end}}$ (for the flow signal a similar state is implemented). So, the following formula is valid:

$$y(t) = Y_{\text{start}} \times \exp(-t/T_c) \text{ for } 0 < t < T_{\text{end}} \quad (3.1)$$

The time constant T_c of this signal has to be estimated from $z(k)$, a sampled version of $y(t)$:

$$z(k) = y(kT_s) \text{ for } k = 0, 1, 2, \dots, (T_{\text{end}}/T_s) \quad (3.2)$$

In (3.2) T_s is the known sample time, which is equal to $(1/F_s)$ with F_s the sample frequency. In our case $F_s = 20$ Hz. In figure 3.4 a graph of $y(t)$ and its samples $y(kT_s)$ is pictured.

From (3.1) and (3.2) we see that when two consecutive samples $z(k)$ and $z(k+1)$ are divided the result is a constant, independent of k :

$$z(k+1)/z(k) = \exp(-T_s/T_c) \quad (3.3)$$

Tests on pressure and flow signals recorded in the OR showed that T_c almost always lays in between 0.3 and 1.5 sec. In our algorithm we take an extra

safety margin of 50% of the lower boundary value and assume that $T_c > 0.15$ sec.
 Filling this in in (3.3) gives:

$$0.7 < (z(k+1)/z(k)) < 1, \text{ for } T_c > 0.15 \text{ sec.} \quad (3.4)$$

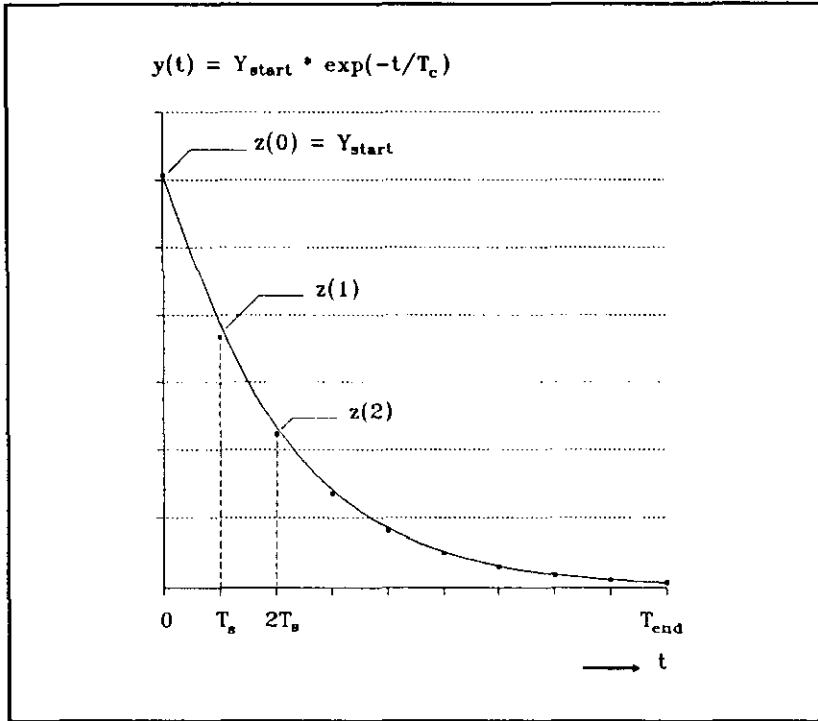


Figure 3.4: Graph of an exponentially decreasing time series.

With $T_s = (1/F_s)$ we get from (3.3):

$$(1/T_c) = -F_s \times \ln(z(k+1)/z(k)) \quad (3.5)$$

Suppose there are n samples available in the decreasing exponential curve, called $z(0)$ up to $z(n-1)$. An estimation of the inverse time constant is given by the following average value (from (3.5)):

$$\langle 1/T_c \rangle = -F_s \times (n-1)^{-1} \times \sum_{i=0}^{n-2} \ln(z(i+1)/z(i)) \quad (3.6)$$

Finally, an estimation of the time constant is given by:

$$[T_c]_{\text{estimated}} = 1/\langle 1/T_c \rangle \quad (3.7)$$

After every new sample $z(i)$ the algorithm divides $z(i)$ by the previous sample $z(i-1)$ and uses a look-up table with the values of $\ln(0.700)$, $\ln(0.701)$, $\ln(0.702)$, ..., $\ln(0.999)$ to get the natural logarithm of the result. This way an updated estimation of the value of $1/T_c$ can be obtained after each sample by updating formula (3.6).

If by accident (for example due to noise) $z(i) > z(i-1)$ the algorithm waits for $z(i+1)$, divides $z(i+1)$ by $z(i-1)$, and if the result lays in between 0.7 and 1 it looks up the natural logarithm of the result. The logarithm is then added to the sum in (3.6) twice, because the time between $z(i+1)$ and $z(i-1)$ is two times T_s . This process goes on until a value $z(i+j)$ is found so that $z(i+j)$ divided by $z(i-1)$ lays in between 0.7 and 1. This method implies that, when very often $z(i) > z(i-1)$, the calculated time constant may be slightly lower than the actual time constant because some samples with a high value are skipped.

If (for example when $T_c < 0.14$) $z(i) < (0.7 \times z(i-1))$ the new sample will be rounded to exactly $(0.7 \times z(i-1))$ and the algorithm goes on to the next sample. So, when $T_c < 0.14$ the result of the time constant estimation will be exactly 0.14. However, as was mentioned earlier, tests showed that the time constant was never lower than 0.3 in clinical situations.

With this algorithm adequate results are obtained very fast, since the time consuming logarithm calculations after each incoming sample are avoided.

3.2.3 Signal Validation

Slope values and time constants are only considered valid if they are based on a minimum number of samples in the respective curve parts. At this moment, a minimum of six samples is required for both features to be valid.

Furthermore, the breath time is stored for every signal after breath detection. The signal processing waits a maximum of 120% of this previous breath time for the next breath detection. If no new breath is detected within this time span the signal is declared invalid and a time-out flag is set. When a signal is invalid all of its features are considered invalid for that particular breath period. By setting a time-out flag the system is prevented from waiting forever until a breath is detected.

When all the numerical feature values are available (after breath detection or time-out on all three signals) an extra cross check is performed to test whether the timing variables of the signals are in accordance with each other. For all the valid signals, the inspiration, expiration and breath times are compared. If the data from one signal vary more than 20% from the variables coming from the other two, the signal is declared invalid. In this way the redundancy that is available is used as good as possible for signal validation.

3.3 Symbolic Data

Since the expert system needs symbolic data rather than numerical data as its input the calculated numerical features are translated into symbolic format. Features that are declared invalid (see § 3.2.3) get the symbolic value 'NV' (Not Valid). As Van Oostrom [1] describes the valid feature values are compared to a value that is considered to be "normal" for that feature in a no-malfunction situation. This reference value will be called the "feature baseline" from now on.

At the beginning of an operation, the anesthesiologist currently has to push a "RESET BASELINES"-button when the signals are stationary and he accepts

them as normal. At that moment all baselines will be reset to the current running average of the feature value, thereby assuming that no malfunction is present.

Resetting the baselines is necessary because the set of initial (default) baselines (based on an average adult patient) is often inadequate. The "normal" values depend heavily on the ventilator settings used, demographic patient data (age, weight, sex) and type of operation. Tidal volume, for example, can vary from 100 ml for neonatals to over 1 liter for young athletes.

For every feature a particular low and high threshold is defined, with the baseline of that feature as a reference, in a look-up table. The zone between upper and lower threshold is called the normal band for that feature. For example, assume a default baseline value for the maximum flow of 600 ml/sec. When the low and high thresholds for the maximum flow feature are set to 30% and 20% respectively the normal zone will be the band between 420 and 720 ml/sec.

Also, for each feature a minimum value is defined. When the baseline is below this minimum the thresholds are absolute rather than relative to the baseline to prevent the normal band from becoming too small. This is particularly necessary for features that have a natural baseline close to zero, like minimum flow or inspired CO₂.

At the end of each breath period, each valid feature gets assigned a symbolic value. These values range from 'UC' (UnChanged) when the feature value lays within the normal band, 'UP' (Up) when the feature value lays above the upper threshold, to 'DN' (Down) when the feature value is smaller than the lower threshold. The set of symbolic values ('UP', 'DN', 'UC', 'NV') serves as input to the expert system after each breath period.

3.4 The Real Time Expert System Approach

The goal for the first prototype of the Intelligent Alarms System is to provide the user with a conclusion about the integrity of the anesthesia breathing

circle after every breath period. Van Oostrom [1] explains the reasons for choosing the SIMPLEXYS Expert System Language, developed at the Eindhoven University of Technology, Eindhoven, The Netherlands by Blom [25,26] as a tool for our implementation. The main advantage of SIMPLEXYS is the fact that it provides "hooks" to a high level programming language (currently, SIMPLEXYS versions for Pascal and for C are available) and therefore data acquisition and graphical user interface routines can easily be interfaced with the expert system body. After compilation, this provides a fast and efficient program. The SIMPLEXYS language was especially designed for real time expert system applications.

The expert system body consists of a set of rules, that contain the expert knowledge in the system. Starting with one or more "root" rules the complete rule set (or a part of the rule set) is evaluated after every breath. Every rule to be evaluated gets assigned a value 'TR' (True), 'FA' (False) or 'PO' (Possible). Depending on the result other rules may be triggered and evaluated as a consequence.

For every malfunction in the breathing circle to be detected, a rule describes how different feature values change when this malfunction occurs. In order to make every rule unique, some features that remain unchanged ('UC') can also be added to the rule. Van Oostrom [1] gives the complete set of rules in the prototype I system. This preliminary rule set was the result of extensive research and discussions with anesthesiologists (the "experts").

In order to make clear how the rule evaluation concept works a **simplified** version of some of the SIMPLEXYS rules is given in table 3.1.

Every SIMPLEXYS run starts with looking at one or more rules of the "STATE" type. Each rule of this type has one or more "GOALS". The rules to be evaluated next are the GOALS belonging to the STATE rule(s) with value 'TR' (True). So, in table 3.1 the rule that checks whether there is no malfunction in the breathing circle (BREATHING_SYSTEM_OK) is always evaluated first. This rule is composed of different "subrules" like the rules that test for incompetent

Table 3.1: Example of some SIMPLEXYS rules.

RUNNING: 'The breathing circuit expert is up and running'
STATE
INITIALLY TR
THEN GOAL: BREATHING_SYSTEM_OK

BREATHING_SYSTEM_OK: 'No malfunctions in the breathing circle'
NOT (INC_VALVE OR OBSTRUCTION OR LEAK OR DISCONNECT OR
EXH_CO2_ABSORBER)

OBSTRUCTION: 'An obstruction is detected'
OBST_ET_TUBE OR OBST_INSP_HOSE OR OBST_EXP_HOSE OR
OBST_VENT_HOSE

OBST_ET_TUBE: 'An obstruction in the E.T. tube is detected'
PRS_MAX_UP AND PRS_SLOPE_UP AND NOT FLW_MAX_UP AND
FLW_T_CONST_UP
THEN DO write_alarm('Obstruction Y-piece or E.T. tube');
THEN FA: OBST_INSP_HOSE, OBST_EXP_HOSE

PRS_MAX_UP: 'The maximum pressure feature is above the normal band'
BTEST (Maxpres == UP)

valves (INC_VALVE) or obstructions (OBSTRUCTION) somewhere in the circle. The OBSTRUCTION rule is again composed of subrules that look at the **site** of the obstruction, like OBST_ET_TUBE.

Finally, at this level the system looks at the symbolic feature values that are fed to the expert system to come to a conclusion. Negatives in the rules are added to make them unique or to prevent unnecessary alarms. For example, when the pressure goes slightly up but the expired maximum flow value is also higher than normal the patient is still ventilated well, so no alarms need to be generated yet. The "THEN DO" section of OBST_ET_TUBE provides a hook to C, if the rule gets assigned a value 'TR' the C code on the rest of the line is

executed. In this case this means that an alarm message is put on the screen. The rules after "THEN FA:" are immediately set to 'FA' without evaluation. The word "BTEST" provides a second hook to C; the C code on the remainder of the line is executed and the rule is set to the result of this boolean test. So, the rule PRS_MAX_UP will get the value 'TR' when the C-variable Maxpres (one of the symbolic features) has a value UP. This means that the maximum pressure feature is higher than the upper boundary of the "normal zone" (see § 3.3).

In the same way the whole rule base is constructed, as can be seen from table 3.1 this setup is much like a tree structure. In the real implementation an alarm message is only put on the screen when the same alarm has been triggered during two consecutive runs. When an alarm is detected for the first time a general "CAUTION" message is generated. This is a protection against false alarms due to motion artifacts of the patient or other external disturbances.

3.5 Software Upgrades

Compared to the preliminary prototype I system that Van Oostrom [1] describes some important changes have been implemented before testing the prototype. Some of them have already been mentioned, like the new algorithms for slope and time constant estimation, the use of an AD-board to sample the pressure and CO₂ waveforms (§ 3.2) and the possibility to set the threshold values for every feature separately instead of using a general margin of $\pm 20\%$ (§ 3.3). Other important changes are mentioned below:

- The flow, pressure and CO₂ signal processing is done using fixed point rather than floating point calculation where possible, in order to increase program speed.

- A new C version of SIMPLEXYS has become available. Since the signal processing as well as the feature extraction software was already written in C the Pascal routines in the expert system body were translated into C.
- The use of MultiDos-Plus as a multitasking extension to the MS-DOS operating system caused a lot of overhead because lots of data had to be sent from one task to another and back. Therefore we choose to pause the signal processing during the feature extraction and expert system evaluation that is performed once a breath. The incoming samples are stored in a buffer during this short period since the three different programs (signal processing, feature extraction, rule evaluation) do not run concurrently anymore. Because all the functional parts are now in the same program all pertinent data is automatically accessible for all routines. Since the C version of SIMPLEXYS is able to evaluate approximately 2000 rules per second, and the prototype I system contains about 60 rules, the "pause" period is very short and provides no problems for the data acquisition.
- The one-program approach also overcomes the major drawback imposed by MultiDos-Plus: no support for high resolution graphics. Thus, the real time graphs of the CO₂, pressure and flow waveforms can be presented on the same screen as the alarm messages now. The raw samples do not have to be sent to a second PC anymore, the whole system is implemented on one IBM AT compatible computer.
- Datalogging capabilities for storing the raw flow, pressure and CO₂ data on hard disk are implemented.
- The rule set is extended with rules that perform extra signal validation checks before the malfunction detection starts.

CHAPTER 4: TESTING PROTOTYPE I

The system described in chapter 3 has been tested in a clinical environment as well as on an anesthesia simulator. The protocol and the results of these tests are presented in the next sections. At the end of the chapter the limitations of Prototype I and the improvements to be made in a second prototype system are summarized.

4.1 Simulator Testing

Before going into the operating room (OR) with the system its performance was tested on the Gainesville Anesthesia Simulator, developed by Good et al. at the University of Florida, Gainesville, U.S.A. [27]. The simulator consists of an Ohmeda Modulus II Anesthesia Machine together with an Ohmeda 7800 series ventilator and the standard monitoring equipment used in the OR. Using a standard breathing circuit and endotracheal (E.T.) tube a mechanical lung is ventilated. Carbon dioxide (CO_2) is fed to the lung to simulate the CO_2 production of the patient. The signals we are interested in, airway pressure in the inspiratory hose, airway flow through the expiratory hose, and partial CO_2 pressure at the Y-piece, are obtained with exactly the same monitors as they would be in the OR.

A number of sensors and actuators makes it possible to introduce mechanical malfunctions in the breathing circuit or anesthesia machine. These include a stuck inspiratory or expiratory valve, an exhausted CO_2 absorber and leaks at different sites. By manipulating circulation-related variables and signals, like the oxygen (O_2) saturation of the blood, the electro-cardiogram (ECG), and the blood pressure, also patient-related mishaps like hypoxia (the O_2 saturation of the blood is too low) and deep or light anesthesia can be simulated. Since blood circulation is not really present in the simulator these signals are generated by software rather than physically measured.

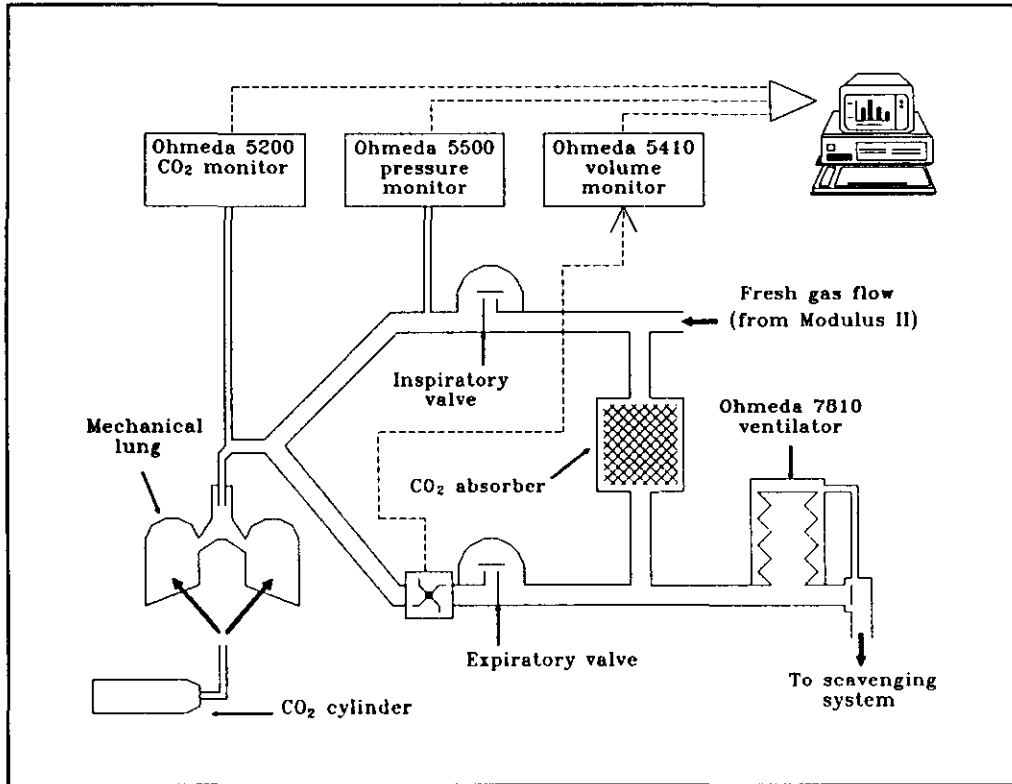


Figure 4.1: Schematic of the test setup with the Gainesville Anesthesia Simulator. The dashed lines represent electrical signals.

The original purpose of the simulator was to teach anesthesiologists how to react on rare catastrophic events during anesthesia. With the simulator the clinician can practice his reactions to mishaps, and even make mistakes without the stress of exposing a real patient to a life-threatening condition. Since the malfunctions we would want to detect never can be introduced during real anesthesia, the simulator is the ideal testbench for the Intelligent Alarm System.

The simulator setup and the locations of the sensors used by our system are schematically pictured in figure 4.1¹.

¹ Figure 4.1 is based partly on a drawing of the anesthesia system by J.S. Gravenstein, MD.

4.1.1 Test Protocol and Results

Using 4 different combinations of ventilator- and fresh gas flow (FGF) settings, a number of malfunctions was introduced (one at a time). During a maximum of 30 seconds or 5 breath periods, whichever came first, the alarm system was expected to detect a malfunction and generate the correct alarm message. After that period the system was brought back into the "no-malfunction" state, and subsequently the next critical event was simulated.

Whenever settings were changed we waited until the system had adapted to the new signals (this usually takes about 5 or 6 breath periods) and then reset the feature baselines to their new running average value (see § 3.3). This was necessary in order to avoid false alarms or missed detections due to the fact that the baselines were not adequate for the setting combination.

The different combinations of ventilator- and FGF settings are given in table 4.1. The compliance of the mechanical lung was set to 0.1 l/cmH₂O, which resembles a normal lung compliance value of an adult patient.

The malfunctions introduced by the simulator were: incompetent expiratory valve, incompetent inspiratory valve, exhausted CO₂ absorber, disconnect of the ventilator hose, CO₂ canister leak, and a leak in the E.T. tube cuff. Manually introduced were: leaks in different hoses, obstructions of different hoses and disconnections of hoses other than the ventilator hose.

Table 4.1: Setting combinations used during the tests at the simulator.

Setting no.	V _T (ml)	RR (breaths/min)	I:E	FGF (l/min)
1	500	12	1:2	6
2	500	12	1:2	3
3	750	6	1:2	6
4	750	6	1:2	3

Leaks of two different sizes were introduced in the various hoses by connecting an open tube with a length of 7.5 cm and a diameter of either 1.5 mm (small leak) or 3 mm (large leak) to the system at the respective locations. Obstructions were simulated by pinching the hoses.

For setting combination 1 the critical events were repeated 4 times to test the consistency of the system. The results of all the tests are given in the matrix in table 4.2. In this table, two different locations for leaks in the expiratory hose can be distinguished. Leak 1 was introduced upstream (at the lung side) of the flow sensor connection, while leak 2 was inserted downstream of the flow sensor. In the matrix an 'X' indicates that the correct (or best available) alarm message was generated within the 30 seconds time span, an 'N' means that no alarm was triggered at all, and an 'F' means that only false alarm messages were generated. When more alarm messages appeared indicating the system detected more than one possible malfunction, but the correct message was one of them, the reaction of the system was still considered correct.

From table 4.2 we see that from the total of 189 events simulated, 167 were detected correctly, while 20 were not detected and 2 false alarms were recorded. This means that 88% of the mishaps was detected correctly within 30 seconds. The two false alarms were an "incompetent inspiratory valve" message, at a small and at a large leak in the E.T. tube.

To explain the false alarms, the essential parts of the rules for incompetent valve, large leak, and small leak are given in table 4.3. When leaks were introduced at the E.T. tube we observed that the CO₂ down stroke sometimes went down. In that case, the only difference between a small leak and an incompetent valve is the maximum flow feature. The difference between a large leak and a stuck inspiratory valve is the fact that the pressure should go down in case of a large leak and remain unchanged during a stuck valve. Since the maximum pressure did not change the false alarms were generated. This problem was solved after the test procedure by changing the rules so that, when the pressure is not going down during a leak in the E.T. tube, two "possible

Table 4.2: Matrix with test results of IASA prototype I on the Gainesville Anesthesia Simulator.

Malfunction	Setting 1	Setting 2	Setting 3	Setting 4
Stuck exp. valve	X X X X	X	X	X
Stuck insp. valve	X X X X	X	X	X
Exh. CO ₂ absorber	X X X X	X	X	X
Obstr. insp. hose	X X X X	X	X	X
Obstr. E.T. tube	X X X X	X	X	X
Obstr. exp. hose	X X X X	X	X	X
Obstr. vent. hose	X X X X	X	X	X
Small leak E.T. tube	F X X X	X	X	X
Small leak Y-piece	X X X X	X	X	X
Small leak insp. hose	X X X X	X	X	X
Small leak 1, exp. hose	X X X X	X	X	X
Small leak 2, exp. hose	N N N N	N	N	X
Small leak vent. hose	N N N X	N	X	X
Large leak E.T. tube	F X X X	X	X	X
Large leak Y-piece	N X X X	X	X	X
Large leak insp. hose	N X X X	X	X	X
Large leak 1, exp. hose	N X X X	X	X	X
Large leak 2, exp. hose	N N N N	N	N	N
Large leak vent. hose	X X X X	X	X	X
E.T. tube cuff leak	X X X X	X	X	X
CO ₂ canister leak	X X X X	X	X	X
Disc. FGF hose	X X X X	X	X	X
Disc. vent. hose	X X X X	X	X	X
Disc. insp. hose	X X X X	X	X	X
Disc. exp. hose	X X X X	X	X	X
Disc. Y-piece	X X X X	X	X	X
Disc. E.T. tube	X X X X	X	X	X

Table 4.3: Expert system rules for three malfunctions.

INCOMP_INS_VALVE: 'A stuck inspiratory valve is detected'
FLW_EXP_VOL_DOWN AND FLW_MAX_DOWN AND CO2_DO_STR_DOWN AND PRS_MAX_NORMAL
SMALL_LEAK: 'A small leak is detected'
FLW_EXP_VOL_DOWN AND NOT FLW_MAX_DOWN AND PRS_MAX_NORMAL
LARGE_LEAK: 'A large leak is detected'
FLW_EXP_VOL_DOWN AND PRS_MAX_DOWN

malfunction" messages are generated: "incompetent inspiratory valve" and "small leak". This can be done by removing the "NOT FLW_MAX_DOWN" part from the SMALL_LEAK rule (see table 4.3).

Of the not detected malfunctions, 13 were leaks introduced directly downstream of the flow monitor but still upstream of the expiratory valve. Because the tidal volume loss due to the leak took place entirely downstream of the flow sensor in this case, the flow signal indicated no (or very little) volume loss. Therefore no leak message was generated. Leaks at that position turned out to be very difficult to detect without extra information. This malfunction is not immediately clinically dangerous, however. Without the leaks at site 2 in the expiratory hose, 95% of the malfunctions was detected correctly.

As a last experiment, the speed of the alarm system program was tested by gradually increasing the respiratory rate (RR) setting on the ventilator. It turned out that the software could keep up with RR values as high as 60 breaths/min. This is much higher than normal rates used during clinical anesthesia (up to 30 breaths/min for pediatrics). Fault detection performance was not tested for higher RR values. This will be done with the prototype II system.

4.2 OR Testing

As a second test, the system was taken to the OR. The CO₂, pressure, and flow monitors were connected to the breathing circuit in the same way as pictured in figure 4.1 during 11 surgery cases of different type. The anesthesia machine used was an Ohmeda Modulus II. The operations included pediatrics, airway/nose surgery, abdominal surgery, heart surgery, liver surgery, ankle surgery with light anesthesia and eye surgery. The ages of the patients varied from 12 months to 75 years, 8 female and 3 male patients were involved. Data from the three monitors were recorded and the system's performance was evaluated in the hostile and noisy OR environment. Of course, no malfunctions could be introduced, we only tested the system for false alarms.

To show how the signals are influenced by external or patient conditions in the OR two examples are given in figures 4.2 and 4.3. In figure 4.2 the CO₂ signal is disturbed by "cardiogenic oscillations", the heart rhythm influences the CO₂ signal at the end of the expiration phase. As a result the CO₂ down slope feature will be unreliable. In figure 4.3 the pressure signal is disturbed because the surgeon is pushing on the patient's chest. The pressure signal is invalid for one or two breath periods. As can be seen from the two figures, the signal processing algorithms must be very robust, because clinical signals are by far not as smooth as those measured with the simulator.

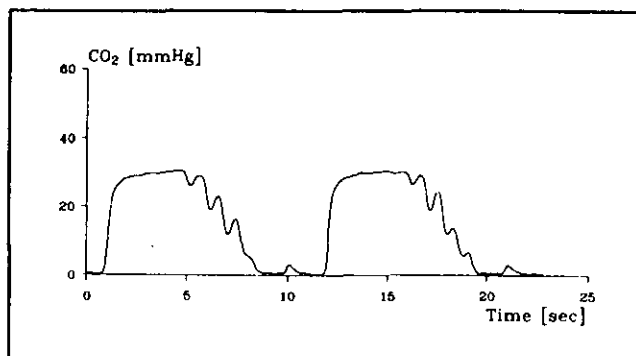


Figure 4.2: Example of a disturbed CO₂ waveform.

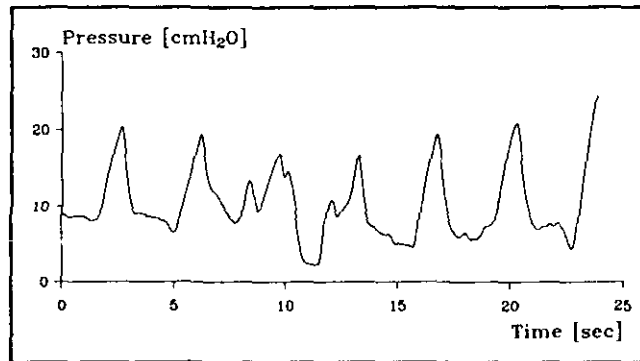


Figure 4.3: Example of a disturbed pressure waveform.

The results of the OR tests can be summarized as:

- Like on the simulator, the system could be "fooled" when the anesthesiologist changed the ventilator settings and/or the fresh gas flow and the feature baselines were not subsequently reset to their new running average value. For example, when the V_T -setting or the FGF-setting was decreased a "small leak" or "large leak" message was generated during several operations.
- Our method of using the serial port of the computer for counting pulses coming from the 5410 volume monitor to generate a real time flow signal (see § 3.2) turned out to be sensitive to electrocautery (BOVI). BOVI sometimes caused high frequency interference on the flow signal.
- When the surgeon was pushing the abdomen or chest of the patient one or more of the signals were sometimes considered "invalid" by the alarm system (see chapter 3). Despite this fact the system most of the times was able to generate the correct "decreased compliance" message. The signals were never invalid longer than two breath periods. In general the patient data were smooth enough to allow correct calculation of the signal features during nearly the entire operations.

- When an artificial nose (a device inserted between the Y-piece and the E.T. tube to moisten the inhaled gases) was used the airway resistance sometimes went up. This was due to water partially blocking the airway inside the artificial nose. As a result a correct "obstruction E.T. tube" message was generated. When the anesthesiologist accidentally pushed the E.T. tube too far in the patient's trachea this was also recognized as an obstruction in the E.T. tube. Finally, a plugged E.T. tube was correctly diagnosed as "obstruction E.T. tube / Y-piece"; after the tube was suctioned the alarm disappeared.
- Although the system is not designed to support manual ventilation it should not generate all kinds of alarm messages in those instances. During the OR tests the prototype I system only generated "CAUTION" messages during periods of manual ventilation, which means that no alarm was triggered for more than one consecutive breath period.
- Two disconnects in the E.T. tube were diagnosed correctly, as was a not completely inflated E.T. tube cuff. The latter one was recognized as a "small leak E.T. tube / Y-piece". No critical event went by undetected.
- The system could easily keep up (real time) with pediatric respiratory rates of 20 breaths/min or more. Also, the low pediatric tidal volumes did not present any problems for the breath detection algorithms.

4.3 Final Conclusions about the First IASA Prototype

As a general conclusion, prototype I worked as expected on simulator data as well as on noisy (compared to the simulator) patient data. Tests showed that the complete system was about three times as fast as real time on an 8 MHz IBM AT compatible computer with a coprocessor and an EGA videocard installed.

Data was read from a file rather than obtained from the monitors during these speed tests. However, some improvements still have to be made.

The most important limitation of the first prototype is the fact that the feature baselines have to be reset after every change in ventilator- or FGF settings. One of the major goals for the second version is to implement an automatic baseline reset. This should prevent false alarms and missed detections due to setting changes.

Another issue is the fact that the system does not consider a "flat" signal and an "invalid" signal as fundamentally different. Implementation of an extra "signal flat" status will also be performed in the second version.

CHAPTER 5: IASA: THE SECOND PROTOTYPE

As mentioned in paragraph 4.3 the most important limitation of prototype I is that the user must reset the feature baselines (see § 3.3) whenever he changes the ventilator or fresh gas flow settings (a setting change is performed very often in clinical practice). If he fails to do so the alarm system may generate false alarm messages or miss occurring critical events. The main goal of prototype II is to implement a feature baseline reset that is performed automatically whenever one or more of the settings in the anesthesia system is changed. The prototype II system should detect malfunctions occurring in the breathing circuit or the ventilator system, patient related malfunctions will not be incorporated yet. The second major goal is to devise a user friendly interface screen for the intelligent alarm system. Theory and implementation of all important new attributes of IASA prototype II are presented in this chapter.

5.1 The Automatic Baseline Reset

First of all the requirements for the automatic baseline reset routine need to be defined. This is done in the next sections. Subsequently the implementation of the automatic reset in the intelligent alarm software is discussed.

5.1.1 When to Reset the Feature Baselines

The feature baselines have to be recalculated after a change in one or more of the settings. On the ventilator, a change in the set tidal volume (V_T), the set respiratory rate (RR) or the set ratio of inspiration to expiration time (I:E), will have effects on the "normal" values of certain signal features. A change in the fresh gas flow (FGF) setting on the anesthesia machine also results in baseline changes, since it affects the delivered tidal volume and therefore the flow and pressure related features.

The anesthesiologist may, for therapeutic reasons, also apply a certain amount of positive end expiratory pressure (PEEP) to the breathing circuit. This has the effect that the pressure does not go to zero after expiration, but remains at the higher PEEP level (much like an offset voltage in an electrical circuit). As a result, the patient's lungs remain partially inflated after expiration, which will improve gas exchange. In most modern anesthesia systems, the PEEP value can be regulated by a control knob mounted on the expiratory valve. A change in applied PEEP will influence some of the feature baselines, like those for minimum and maximum pressure.

Other parameters the clinician can regulate on the anesthesia machine are related to gas composition. However, a change in gas composition will only affect patient-related variables, and not those associated with the breathing circuit or the ventilator.

Thus, in order to know when to recalculate the feature baselines, changes in V_T , RR, I:E, FGF and PEEP need to be detected. Since a rule evaluation is performed once during each breath period (see chapter 3), it is sufficient to collect the updated setting values after each breath detection.

5.1.2 Which Feature Baselines Change?

In this section we determine which feature baselines actually should be recalculated after setting changes. As a result of some assumptions we make, not all of the "normal values" for the signal features mentioned in § 3.2.2 need to be recalculated.

In a first approximation, we assume that the carbon dioxide (CO_2) up slope, down slope, and end tidal plateau value are not influenced by a change in V_T , FGF or PEEP. The up slope and the down slope will change slightly when the gas flow in and out of the lungs is altered (CO_2 transport is faster with higher flows), but tests showed that these changes usually lay within the tolerance zone of our slope calculation. The slopes should always be very steep in no-malfunction

situations and considerably less steep when, for example, the inspiratory valve is stuck. In the latter case, expiration takes partly place through the inspiratory hose, and as a result expired (CO_2 rich) gas is reinspired at the next breath. This causes the CO_2 down slope to be less steep than normal.

The end tidal CO_2 value (P_{etCO_2}) depends on gas composition, minute ventilation, and demographic patient data. In our first approximation, however, we assume P_{etCO_2} is independent of the settings. When the concept of the baseline reset, described below, is proven, a simple patient model may be incorporated in the alarm system. This should lead to the automatic calculation of new baselines for P_{etCO_2} and for the slope values after, for example, the gas composition is changed.

The expected value for minimum expiratory flow (F_{min}) and for inspired CO_2 (P_{iCO_2}) will always be zero, independent of the setting values.

The value of the time constant of the pressure and flow down stroke depends on the resistance of the tubing and airway, the compliance of the tubing and the compliance of the lungs. The first two factors are equipment related and thus constant and completely independent of the settings. The compliance of the lungs may change during surgery, for example after the chest is opened. In our first approximation we elected the automatic baseline reset only to be performed after setting changes, not when the patient's condition changes. This means that we consider the time constants of the flow (T_F) and pressure signal (T_P) as constant. The clinician will still have to reset the feature baselines to their running average value manually (by pushing the "RESET BASELINES" button, see § 3.3) when, due to mutations in the patient's condition, changes in the signals occur.

This leaves the time related variables (inspiratory time T_{insp} , expiratory time T_{exp} , and breath time T_{br}) for each signal, and the minimum pressure (P_{min}), the pressure slope value (P_{slope}), the maximum pressure (P_{max}), the maximum flow (F_{max}), and the measured expired tidal volume (V_{Tmea}) as the features for which new baselines have to be calculated after setting changes.

5.1.3 Simple Breathing Circuit Modeling

Van Oostrom [28] derived some formulas for the variables mentioned in § 5.1.2. The basis for the derivations is a simple first order electrical model for the pressure and flow signals in the breathing circle. In figure 5.1 the electrical model for the inspiration is pictured, while in figure 5.2 the expiratory model is given.

During inspiration the ventilator acts as a current source: a constant flow F_I is forced into the lungs through the inspiratory hose, while the expiratory flow F_E is zero. At expiration, the driving force of the ventilator is removed, the flow through the inspiratory hose F_I equals zero, and the lungs empty passively through the expiratory hose until the pressure in the lungs equals the PEEP value.

The symbols in figures 5.1 and 5.2 have the following meaning:

- R: resistance of the inspiratory, respectively the expiratory tubing, plus the resistance of the patient's airway,
- C: combined compliance of lungs and tubing,
- F_I : inspiratory flow,
- F_E : expiratory flow,
- P_L : the pressure in the lungs.

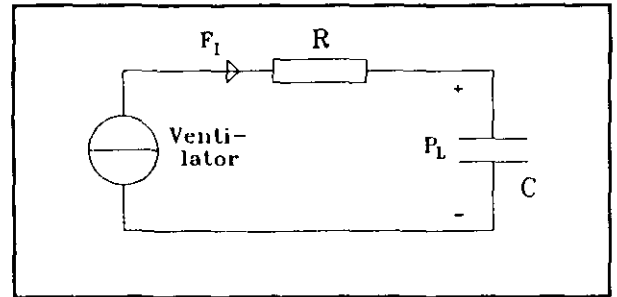


Figure 5.1: Electrical model for inspiration.

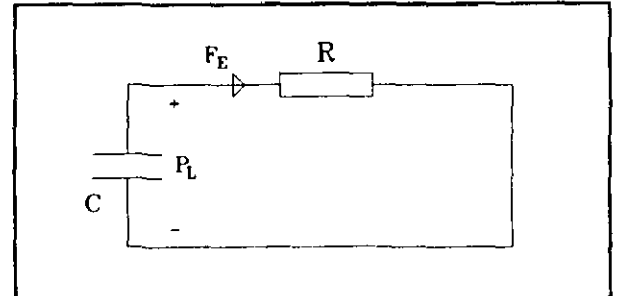


Figure 5.2: Electrical model for expiration.

Van Oostrom [28] derived the following formulas from this model, assuming that the peak pressure in the lungs is equal to P_{\max} and that the resistance of the inspiratory tubing equals the resistance of the expiratory tubing in a no-malfunction situation:

$$P_{\min} = \text{PEEP} \quad (5.1)$$

$$F_{\max} = V_{\text{Tmea}} / RC \quad (5.2)$$

$$P_{\max} = (R \times F_{\max}) + P_{\min} \quad (5.3)$$

$$P_{\text{slope}} = V_{\text{Tdel}} / (T_{\text{insp}} \times C) \quad (5.4)$$

In this set of formulas V_{Tdel} is the tidal volume actually delivered to the lungs via the inspiratory hose, whereas V_{Tmea} is the tidal volume measured in the expiratory limb of the breathing circle. We assume that:

$$V_{\text{Tmea}} = K \times V_{\text{Tdel}} \quad (5.5)$$

In (5.5) K is a constant independent of the settings. V_{Tdel} depends on the tidal volume actually set on the ventilator (V_{Tset}), on the fresh gas flow setting (FGF, [ml/sec]) and on the set PEEP value. We assume that the fresh gas flow is completely added to the tidal volume during the inspiratory time and is mixed with the expired gases during expiration. So, the contribution of FGF to the delivered tidal volume is equal to $(\text{FGF} \times T_{\text{insp}})$.

In order to build up and maintain the PEEP a certain part of the tidal volume is lost. Experimental measurements showed a tidal volume loss nearly linearly related to the PEEP setting. For a PEEP lower than 10 cmH₂O the loss equaled approximately $(25 \text{ [ml/cmH}_2\text{O]} \times \text{PEEP})$. This results in the following approximation:

$$V_{\text{Tdel}} = V_{\text{Tset}} + (\text{FGF} \times T_{\text{insp}}) - (25.0 \times \text{PEEP}) \quad (5.6)$$

With (5.1) to (5.6) we are able to give all the expected feature values when no malfunction is present as a function of the setting values V_{Tset} , RR, I:E, FGF and PEEP, and the constants R, C, RC, and K (see also [28]):

$$T_{br} [\text{sec}] = 60.0 / \text{RR} [\text{breaths/min}] \quad (5.7)$$

$$T_{insp} [\text{sec}] = ((I:E) \times T_{br}) / (1.0 + (I:E)) \quad (5.8)$$

$$T_{exp} [\text{sec}] = T_{br} - T_{insp} \quad (5.9)$$

$$V_{Tmea} [\text{ml}] = K \times (V_{Tset} + (FGF \times T_{insp}) - (25.0 \times \text{PEEP})) \quad (5.10)$$

$$P_{min} [\text{cmH}_2\text{O}] = \text{PEEP} \quad (5.1)$$

$$F_{max} [\text{ml/sec}] = V_{Tmea} / RC \quad (5.2)$$

$$P_{max} [\text{cmH}_2\text{O}] = (R \times F_{max}) + P_{min} \quad (5.3)$$

$$P_{slope} [\text{cmH}_2\text{O/sec}] = V_{Tmea} / (K \times T_{insp} \times C) \quad (5.11)$$

This set of formulas is used to calculate the new feature baselines when one or more settings have changed. The implementation is discussed in the next section.

5.1.4 Implementation

The Ohmeda 7810 ventilator provides a mode in which all the measured values and all the settings dialed on the front panel of the ventilator are transmitted via its serial port after the user (i.e. the intelligent alarm software) requests these data. Measured values come from several sensors connected to the ventilator: an oxygen (O_2) sensor near the fresh gas outlet, a tidal volume sensor in the expiratory limb and a pressure sensor in the inspiratory limb of the breathing circle. The ventilator is connected to serial port COM1 on the computer used in our prototype. Interrupt code is written that requests new data from the ventilator at the start of each breath period. The incoming string of characters is buffered, and after breath detection converted to numerical values.

This way, an updated set of ventilator settings is available before each expert system run.

In order to measure FGF a second volume monitor is used (Ohmeda 5410). The sensor is inserted into the fresh gas hose (see figure 4.1). Similar to the expiratory flow signal, this monitor generates a pulse for approximately every 3 ml of gas that passes the sensor. The FGF pulse- and direction signals are connected to two unused pins at serial port COM2 in the computer (the expiratory flow signal also comes in at COM2). The interrupt code is modified so that, whenever COM2 generates an interrupt, the system first looks from which flow monitor the pulse originated. Thereafter the respective counter is increased or decreased, depending on the directional signal. After breath detection, the number of FGF pulses is multiplied by 3 ml and divided by the breath time to get the average fresh gas flow during one breath period. The FGF result is corrected for non-linear sensor error by means of a look-up table of correction factors as a function of the average FGF value. The look-up table is created based on the measured inaccuracy of the FGF result at a flow of 100% O₂.

So, at breath detection, a new value for V_{Tset} , RR, I:E, PEEP (all coming from the ventilator) and FGF (coming from the second flow device) is available. These new setting values are compared to the settings **directly after** the most recent baseline reset. If the relative difference is 10% or more, and if FGF > 0 ml/sec (a negative measured FGF value means a disconnect of the fresh gas hose rather than a setting change), new feature baselines are calculated with help of formulas (5.1) to (5.3) and (5.7) to (5.11). After that the current setting values are stored as the new reference values.

However, the constants RC, R, C, and K can show slight changes during the course of anesthesia. The algorithm will update a moving average value for these four constants after each expert run, if 1) a new and valid set of settings is available, 2) all numerical features are declared valid, and 3) no malfunction is detected in the breathing circle. The updated moving average values are obtained by filling in the values of V_{Tmea} , F_{max} , P_{max} , P_{min} , P_{slope} , and T_{insp} calculated by

the signal processing routines, and the new setting values, into formulas (5.1) to (5.3) and (5.7) to (5.11). At these moments, the constants are considered the unknown components in the formulas. This way the algorithm will adapt to slight changes in compliance or resistance due to external circumstances (like the surgeon opening up the patient's chest).

Preliminary tests showed that all assumptions are valid, except the assumption that an increase in PEEP does not influence the constants R , C , RC and K . Whenever the PEEP value is increased, the alarm system is not able to see the difference between a PEEP setting change and an obstruction in the expiratory limb of the breathing circuit. This can be explained by the fact that turning up the PEEP valve physically causes the expiratory resistance to increase. In case of an obstruction the resistance is also increasing. A solution to this problem would be to build a sensor on the PEEP valve that senses when the clinician turns it. Then the system will detect the difference between a change in PEEP setting and a change in minimum pressure as a result of a malfunction. Since this solution was not feasible, the remaining solution is to let the anesthesiologist reset the feature baselines manually after a change in PEEP.

5.2 The User Interface

The basic purpose of the user interface is to show the status of the anesthetic system to the clinician controlling it. The items to be presented on the display screen include the high level states of the anesthetic system and the patient as well as real-time raw signal waveforms monitored. Furthermore, the numerical values of the most important measured patient and equipment related variables is presented.

A schematic of the user interface screen designed for the prototype II system is pictured in figure 5.3. In order to effectively represent the state of the anesthetic system three different types of presentation are implemented. These include a "traffic light", real time graphs, and alpha-numerical messages and

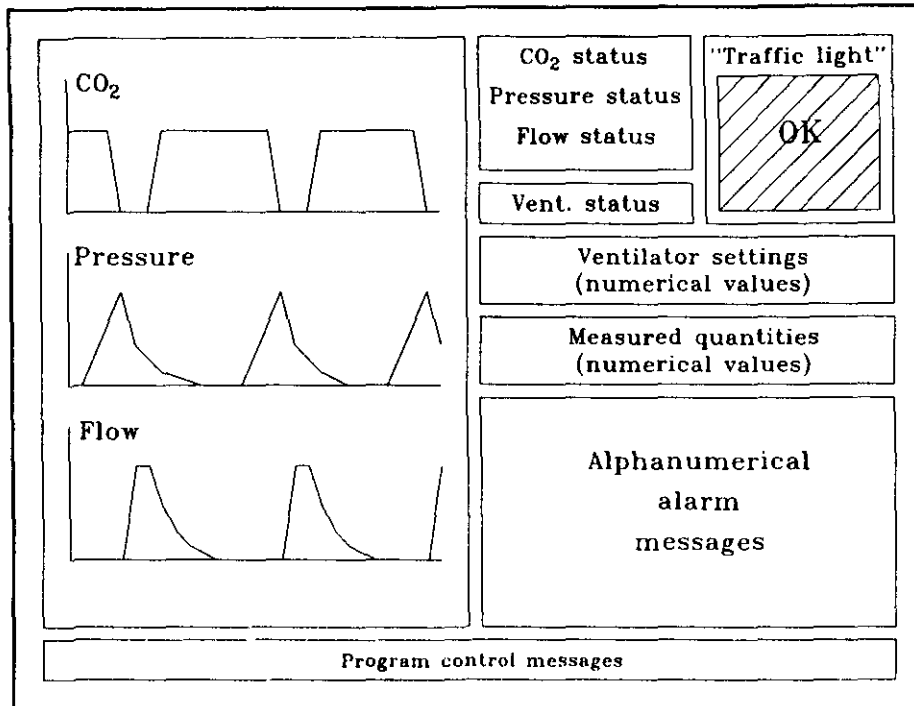


Figure 5.3: User interface display screen.

numbers.

The left half of the screen is used to display waveforms representing the most recent 25 seconds of raw CO_2 , pressure, and flow data. The waveforms serve a "quality control" purpose: when an alarm message would be generated caused by artifacts the clinician will immediately see the artifact in the raw signals.

The colored box in the right upper corner of the screen gives the clinician a first quick insight in the state of the anesthesia system. The box is either green (everything OK), yellow (a "CAUTION" message is generated by the expert system), or red (an "ALARM" condition is detected). The statuses of the 3 signals are also displayed in a "traffic light" fashion. When the signal is OK the message is given in green, an invalid signal is represented by a yellow message and a red notice means that there is no signal detected at all (signal "FLAT"). The ventilator status word indicates whether mechanical ventilation is present or not.

When the system status is "ALARM", an alphanumeric alarm message indicates the most probable malfunction(s), together with its (their) most likely site.

Other information including the system setting values (V_T , RR, I:E, FGF and PEEP), and important measured quantities like the inspired O_2 percentage ($F_I O_2$) and the expired minute volume (MV) is presented in numerical fashion.

Finally, program control messages about possible user inputs are given on the lower line of the screen. Currently, the user can control the system by pushing buttons on the keyboard. He can push the "RESET BASELINES" button, as mentioned earlier, which will overrule any automatic baseline reset and accept the current running average value of all features as new baselines. Furthermore, the user can start and stop recording the raw signal samples on hard disk, suspend the program temporarily when he wants to take a detailed look at waveforms or alarm messages, and abort the program to go back to DOS.

5.3 Software Upgrades

Since one of the final goals of the Intelligent Alarm Project is to centralize alarms coming from different monitors, the alarm messages generated by the ventilator (and transmitted via its serial port) are taken into account and displayed when no "intelligent" message is triggered by the rule set. The ventilator alarms include messages about low gas supply pressure, low and high airway pressure, failing O_2 or tidal volume sensors, low $F_I O_2$, and internal electrical failures. To prevent an enormous number of alarm messages in case of emergency, a "message shell" is implemented. Every alarm message is assigned a certain priority. At the end of each expert system run only the triggered alarms with the highest priority are selected and put on the screen. Every triggered alarm message is written in a file, however. This makes it possible to track back and evaluate the expert system behavior afterward.

Furthermore, an extra "FLAT" status is implemented for the three signals. This way, the expert system will see the difference between no signal at all ("FL") and an invalid signal, for example due to artifacts ("NV"). The symbolic data that serve as input to the expert system can now have a value of either "UP",

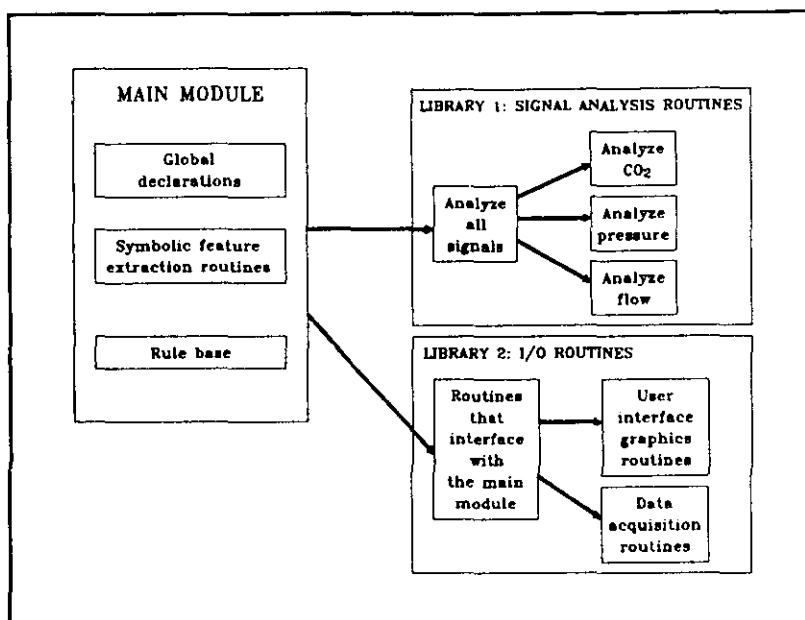


Figure 5.4: Configuration of the IASA prototype II software package.

"DN", "UC", "NV", or "FL" (see also chapter 3).

As a last change, the whole structure of the software package is altered. The new program structure is schematically pictured in figure 5.4. This structure has the advantage that the Intelligent Alarm System software is easily portable from one system to another, since the machine dependent data acquisition and user interface routines are separated from the expert system and signal processing routines. In future, the system can be implemented into an anesthesia machine by only reprogramming the routines that interface the main module with the low level I/O routines.

In appendix 1 all rules at the two highest levels of the rule base tree structure are presented. In appendix 2 a flow chart is given that pictures the data flow in the prototype II alarm system software in a somewhat simplified fashion. In appendix 3 a short formal description of the five routines that interface the main module with the low level I/O routines is presented, while

in appendix 4 a list of detailed technical data regarding the software and hardware composing Prototype II is given.

CHAPTER 6: TESTING PROTOTYPE II

The second prototype described in chapter 5 has been tested similar to the first prototype. Although tests with dogs and, subsequently, tests in the operating room (OR) are planned for the future, prototype II has currently only been tested on the simulator. The results of the simulator testing procedures are summarized in the next sections.

6.1 Single Malfunctions

The test setup with the Gainesville Anesthesia Simulator was the same as described in § 4.1 and pictured in figure 4.1. The second flow device was inserted into the fresh gas hose, and the data from this Ohmeda 5410 volume monitor and the Ohmeda 7810 ventilator were fed to the computer as described in chapter 5. To test the fault detection performance of the system, two test sequences were executed. During each sequence, a number of malfunctions was introduced at different combinations of tidal volume- (V_T), respiratory rate- (RR), ratio of inspiration to expiration time- (I:E), fresh gas flow- (FGF), and positive end expiratory pressure (PEEP) settings. The test protocol was the same as described in § 4.1.1, except for the fact that no manual baseline reset was performed after setting changes other than PEEP changes. The only other time the baselines were reset to their current mean was after system start-up. The compliance of the mechanical lung was set to 0.1 l/cmH₂O.

At the beginning of the first sequence, the following setting values were present: $V_T = 750$ ml, RR = 10 breaths/min, I:E = 1:2, FGF = 5 l/min, and PEEP = 0 cmH₂O (setting 1a). After introducing a number of malfunctions, the FGF setting was lowered to 2 l/min and the experiments were repeated (setting 1b). Finally, V_T was changed to 350 ml, RR to 20 breaths/min and I:E to 1:2.5 (setting 1c). The results of this test sequence are given in table 6.1. As in chapter 4, an 'X' in table 6.1 means that the correct message was generated within

30 seconds or 5 breath periods, an 'F' indicates that only false alarm messages were generated, and an 'N' means that no malfunction message was triggered at all.

Table 6.1: Results of test sequence 1 for Prototype II at the simulator.

Malfunction	Setting 1a	Setting 1b	Setting 1c
Obstr. E.T. tube	X	X	X
Obstr. insp. hose	X	X	X
Obstr. exp. hose	X	X	X
Obstr. vent. hose	X	X	X
Stuck insp. valve	X	X	F
Stuck exp. valve	X	X	X
Exh. CO ₂ absorber	X	X	X
Disc. FGF hose	X	X	X
Disc. Y-piece	X	X	X
Disc. vent. hose	X	X	X
Small leak insp. hose	X	X	X
Small leak exp. hose	X	X	X
Disc. CO ₂ sampling line	X	X	X

When, after a disconnection of the CO₂ sampling line, a "Small leak" or "Large leak" message was generated, the reaction of the alarm system was considered correct.

The only false alarm recorded was a "Small leak" message when the inspiratory valve was stuck. At a high RR value, the increase in the down slope of the CO₂ signal was not sufficient to trigger the "Incompetent inspiratory valve" message (see also § 4.1.1 and table 4.3). The automatic baseline reset worked as expected during this first test.

The setting combinations used during the second test sequence are given in table 6.2. Again, no manual baseline reset was performed after transitions from setting 2a to 2b, and 2b to 2c. As explained in chapter 5, the feature baselines had to be reset manually after the PEEP change during the transition from setting combination 2c to 2d. The test results are presented in table 6.3.

Table 6.2: Settings during the second test sequence for Prototype II.

Setting	V _T (ml)	RR (br/min)	I:E	FGF (l/min)	PEEP (cmH ₂ O)
2a	300	15	1:2	3	0
2b	500	12	1:2	5	0
2c	750	10	1:2	8	0
2d	750	10	1:2	8	7

Table 6.3: Results of test sequence 2 for Prototype II at the simulator.

Malfunction	Setting 2a	Setting 2b	Setting 2c	Setting 2d
Large leak insp. hose	X	X	X	X
Large leak exp. hose	X	X	X	X
Disc. CO ₂ sampling line	X	X	X	X
Small leak insp. hose	X	X	X	X
Small leak Y-piece	X	X	X	X
Small leak exp. hose	X	X	X	X
Disc. FGF hose	X	X	X	X
Stuck insp. valve	X	X	F	F
Obstr. insp. hose	X	X	X	X
Obstr. E.T. tube	X	X	X	X
Obstr. exp. hose	X	X	X	X
Obstr. vent. hose	X	X	X	X

The automatic baseline reset again worked without errors, the calculated "normal" values always laid within 10% of the actual feature values after baseline changes, and no false alarm messages due to wrong baseline recalculation were recorded.

The two false alarm messages were a "Small leak" message at setting 2c, and an "Apnea" alarm at setting 2d, both when the inspiratory valve was stuck. At a high FGF value (setting 2c), the CO₂ down slope feature did not increase sufficiently after introduction of the malfunction, so the correct alarm message was not triggered. Furthermore, when the inspiratory valve was stuck and a high PEEP value was applied (setting 2d), the expiratory flow returned completely (not

partly, as in situations with low or no PEEP) through the inspiratory hose. In this case, the stuck valve provided a "short circuit" from the lungs to the part of the breathing circle located on the machine side of the valves, where no PEEP was present. As a result, the measured flow signal was flat, no breath detection could be performed on this signal, and no intelligent alarm was generated (since the pressure signal remained unchanged).

Currently, a discussion is going on about possible improvements in the detection of the inspiratory valve malfunction. The current rule uses the assumption that the CO_2 down slope becomes less steep when the valve is stuck. The tests showed that this is not always the case, during high RR or FGF values the detection was unreliable. A possible solution is to make the thresholds that define the "normal band" for each feature adaptive. When the quality of the signal is very high, the normal band can become smaller, so that very small changes are already detected. This way, when a smooth CO_2 signal is available, an increase of, for example, 5% instead of 20% in the CO_2 down slope value could already trigger the "Incompetent inspiratory valve" message. Problem with this method, however, is that we have to define and calculate a reliable "signal quality index".

Furthermore, an improved PEEP model has to be implemented to accommodate for the changes in the signals during high PEEP. The current simple estimation (formula 5.10), in which only the measured tidal volume is corrected for PEEP, turned out to be insufficient. Close attention has to be paid to the complexity of this model, however. Since the alarm system must be able to give correct messages in many different situations, the implemented models must be kept as simple and robust as possible.

Apart from the issues mentioned above, the overall detection performance was good. Of 87 malfunctions introduced, 84 were detected correctly within the 30 seconds time span. This means that 95.5% of the faults were recognized by the system.

6.2 Multiple Malfunctions

Although theoretically the probability of multiple malfunctions occurring at the same time is extremely small, we tested the system for a few combinations of malfunctions. The goal of these tests was to make sure that the alarm scheme generates reasonable messages during multiple malfunctions, and that no "nonsense messages" are presented. The results of these experiments are given in table 6.4, the settings were the same as setting 1a (see § 6.1).

Table 6.4: Test results for Prototype II during multiple malfunctions.

Malfunctions	Triggered alarm message(s)
Small leak exp. hose + Obstr. exp. hose	* Obstruction exp. or vent. hose
Stuck insp. valve + Obstr. exp. hose	* Incompetent inspiratory valve * Small leak, site unknown or (when complete occlusion) * Apnea
Stuck insp. valve + Small leak exp. hose	* Incompetent inspiratory valve * Small leak, site unknown
Stuck insp. valve + Stuck exp. valve	* Incompetent expiratory valve
Obstr. exp. hose + Obstr. insp. hose	* Obstruction E.T. tube/Y-piece

As can be seen from table 6.4, in nearly all cases at least one of the triggered alarm messages was a correct one. When a combination of a stuck inspiratory valve and a complete obstruction of the expiratory hose is introduced the incorrect "Apnea" message is triggered. This situation can be compared to the stuck inspiratory valve in combination with a high PEEP setting described in § 6.1. Since the flow signal becomes completely flat this alarm is generated by the

ventilator. Because no other intelligent alarm message is triggered the ventilator message is copied by the system and displayed on the screen.

When the inspiratory and the expiratory hose are obstructed simultaneously, the logical result is an "Obstruction E.T. tube/Y-piece" message. In both cases both the inspiratory and the expiratory resistance increases, so the pressure and flow signals are influenced in an identical way.

The general result of the preliminary tests of the system behavior during multiple malfunctions is satisfactory. More testing has to be performed in this area in the near future, however.

6.3 Future Testing

Although the performance of the Prototype II system during simulator tests was very good, it has not been exposed to the hostile OR environment yet. Especially the performance of the automatic baseline reset has to be tested carefully in the presence of noisy signals.

Currently a third prototype, in which some patient-related malfunctions will be incorporated, is being developed (see chapter 7). Since not all patient-related mishaps we are interested in can be tested with the anesthesia simulator, we decided to test the Prototype III alarm system on anesthetized dogs, before taking it to the OR for false alarm tests. However, the test sequences with dogs and the OR experiments are very time consuming, whereas the test protocols for prototypes II and III will have many aspects in common. Therefore, we decided to combine the OR test of Prototype II (especially the performance of the automatic baseline reset) with the dog and OR tests of Prototype III (detection performance of patient-related malfunctions).

CHAPTER 7: CONCLUSIONS AND RECOMMENDATIONS

7.1 Conclusions

Tests of the first prototype of the Intelligent Alarm System in Anesthesia (IASA) showed that the system can detect and locate the most important malfunctions that can occur in the circle breathing circuit during general anesthesia. These malfunctions include small and large leaks at various sites, obstructions of different hoses, an exhausted CO₂ absorber, incompetent unidirectional valves, and disconnections at various locations. Detection and identification of malfunctions, introduced with the Gainesville Anesthesia Simulator, occurred correctly within 30 seconds in 88% of the cases.

Furthermore, the system was taken to the operating room (OR) and tested during 11 cases. No false alarms were recorded, while no critical event went by undetected. Also, the signal processing routines were robust enough to handle the noisy and sometimes disturbed signals in the OR.

The second prototype, designed to adapt automatically to changes in the anesthesia system control settings, had a 95.5% correct detection performance during tests with the simulator. All faults that were not detected were not immediately clinically dangerous, however. No errors due to wrong adaptation to a setting change were recorded. Only the detection of an incompetent inspiratory valve turned out to be unreliable: sometimes a wrong alarm message was generated. Also, the system's detection performance was degraded slightly with high values of positive end expiratory pressure (PEEP) in the breathing circuit. This is due to the fact that especially the expiratory flow signal is affected drastically by high PEEP values. Currently, research is conducted to improve the system regarding the latter two issues. Finally, the system was able to generate sensible messages when multiple malfunctions were introduced at the same time.

A disadvantage of the current system is that faults present before the start of anesthesia can be accepted as normal, if undetected by the clinician.

Regarding program speed, tests showed that the system runs about 3 times as fast as real time on an 8 MHz IBM AT compatible computer with coprocessor installed. The system could keep up with respiratory rates (RR) up to 60 breaths/min on the simulator, which is twice as high as the highest RR values regularly used in clinical practice.

All tests indicated that the second IASA prototype has, after further refinement and testing, the potential to be the platform for the development of a highly integrated intelligent alarm system for use during anesthesia. The real time expert system approach proved *relatively easy to implement*, and offers many expansion possibilities. This future alarm system can be a very useful help to the anesthesiologist during the course of anesthesia, since it suppresses unnecessary alarms and, in case of mishaps, it can shorten the time he needs to come to a diagnosis.

7.2 Recommendations for Future Research

Currently, we are developing a third prototype, which will also detect some "malfunctions" occurring in the patient rather than the equipment. The following points summarize possible improvements or additions to the Intelligent Alarm System, and suggest extra tests to be performed before a real clinical version can be implemented:

- As mentioned in chapter 6 and § 7.1, a more sophisticated PEEP model needs to be incorporated in the system. Subsequently, the automatic feature baseline reset routines can be fine tuned. Also, the detection rule for the stuck inspiratory valve needs to be revised.
- A Pulse Oximeter has to be interfaced with our alarm system. After that, the oxygen saturation of the blood and the inspired oxygen percentage can be incorporated into the knowledge base as extra variables. This way, the

third IASA prototype will be able to evaluate gas exchange in the lungs, and to give some patient related alarms in addition to the list of detectable mechanical malfunctions.

- Although the current system can automatically recalculate feature baselines after changes in settings (see chapter 5), the **initial** baselines still have to be reset manually by the anesthesiologist when the situation is stable. Some simple patient modeling, combined with the implementation of a possibility to enter basic patient data (age, height, weight, sex) into the system, may lead to automatic calculation of a set of initial feature baselines.

- Prototypes II and III must be tested extensively on anesthetized dogs as well as in the hostile environment of the OR, as mentioned in chapter 6. The clinical usefulness of the system should be evaluated after measuring the number of suppressed unnecessary alarms. Furthermore, more tests with multiple malfunctions occurring at the same time must be performed.

- In order to avoid that the system accepts malfunctions present during system start-up as normal, Prototype II could be used as a platform to develop an automated pre-check procedure for the anesthesia machine. Currently, the clinician has to test the whole system manually before the start of anesthesia.

- As a next step, the system can be expanded to generate simple but useful alarm messages (i.e. evaluate a subset of the current rule set after each breath period) during manual or spontaneous ventilation. The current system is only designed for mechanical ventilation.

- A trend detection scheme for variables like the blood oxygen saturation and the end tidal CO₂ value needs to be designed and implemented.

Analyses of the available medical knowledge, in preparation for representation of the oxygen saturation and the end tidal CO₂ in the knowledge base, showed the need for such addition.

- Further on in the future, more circulation-related signals like blood pressure and the electro-cardiogram may be incorporated into the system, in order to come closer to the final goal of a centralized, integrated alarm system for the patient-equipment combination during anesthesia.

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APPENDIX 1: THE KNOWLEDGE BASE

In the following the rules at the highest two levels of the knowledge base are given:

LEVEL 0:

EXIT: "Exit expert system, go back to DOS"

BTEST (control == 'A')

RUNNING: "Breathing circuit expert up and running"

STATE

INITIALLY TR

THEN GOAL: SIGNALS_OK, VENTILATOR_OK, BREATHING_SYSTEM_OK

LEVEL 1:

SIGNALS_OK: "The signals are all valid"

CO2_SIG_OK UCAND PRS_SIG_OK UCAND FLW_SIG_OK

VENTILATOR_OK: "The ventilator is on and running"

MUST NOT (POWER_OFF OR VENTILATOR_OFF)

THEN GOAL: SETTING_CHANGE, ACCEPT_PEEP_CHANGE

BREATHING_SYSTEM_OK: "No malfunctions in the breathing circuit are detected"

MUST NOT (BS_INC_VALVE UCOR BS_OBSTRUCTIONS UCOR BS_LEAKS UCOR
BS_CO2_ABSORBER UCOR BS_DISCONNECTS UCOR VENT_ALARM)

APPENDIX 2: DATA FLOW IN PROTOTYPE II

In figure I the data flow in the IASA Prototype II software package is (somewhat simplified) schematically pictured.

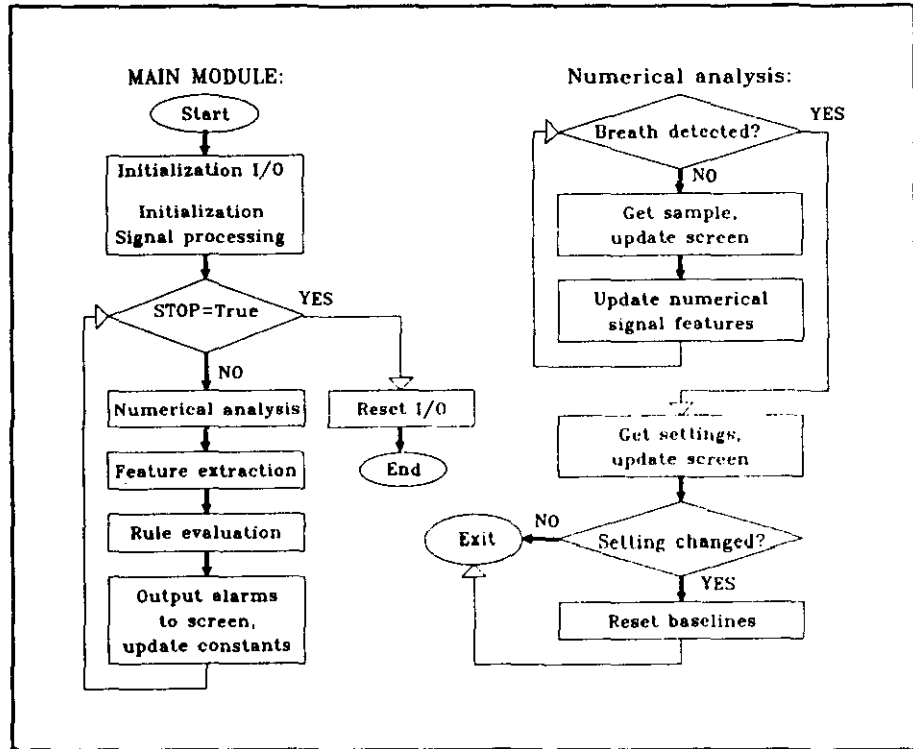


Figure I: Flow chart of the Prototype II software.

APPENDIX 3: FORMAL DESCRIPTION INTERFACE ROUTINES

FUNCTION:

```
int ia_init_io(void);
```

DESCRIPTION:

ia_init_io() performs initializing tasks, i.e. the initialization of the serial communication and the user interface screen, and the opening of datalogging files. This function is called only once directly after program start-up.

CALLING CONVENTION:

```
status = ia_init_io();
```

RETURN VALUE:

1 when error(s) during initialization, otherwise 0.

FUNCTION:

```
int ia_exit_io(void);
```

DESCRIPTION:

ia_exit_io() resets the serial ports and the user interface screen, and closes all open files before exiting to DOS. The function is called only once before aborting the expert system.

CALLING CONVENTION:

```
status = ia_exit_io();
```

RETURN VALUE:

0 when normal exit, 1 when exit due to error(s).

FUNCTION:

```
int ia_get_real_time_sample(struct real_time_data *inpointer);
```

DESCRIPTION:

ia_get_real_time_sample() fills the structure pointed to by inpointer with the next unprocessed raw sample from the CO₂, pressure, and flow signal. The function also updates the real time graphs on the user interface screen, and writes the new data into datalogging files if necessary.

CALLING CONVENTION:

```
status = ia_get_real_time_sample(&sample);
```

RETURN VALUE:

0 when no errors occur during data acquisition, 1 when data is invalid or when one or more monitors are not connected, and -1 when a fatal error occurs during data acquisition (failure of the AD-board or data overrun).

FUNCTION:

```
int ia_get_breath_by_breath_data(struct breath_by_breath_data_in *inpointer);
```

DESCRIPTION:

`ia_get_breath_by_breath_data()` fills the structure pointed to by `inpointer` with the latest complete set of ventilator and fresh gas flow data, and gives an indication about the validity of the data set in the return value. Also, the screen and the logfile are updated with the new settings. The function is called before each rule evaluation.

CALLING CONVENTION:

```
status = ia_get_breath_by_breath_data(&breath_data_in);
```

RETURN VALUE:

0 when the structure is filled with a new and complete data set, 1 when data are invalid or no new data are available yet, and -1 when a fatal error occurs during data acquisition.

FUNCTION:

```
int ia_put_breath_by_breath_data(  
    struct breath_by_breath_data_out *outpointer);
```

DESCRIPTION:

ia_put_breath_by_breath_data() fills the structure pointed to by outpointer with all the statuses and alarm message strings that were triggered during the last expert system run. The highest priority alarms are printed on the user interface screen, and the messages are written in a datalogging file. The function is called directly after each rule evaluation.

CALLING CONVENTION:

```
status = ia_put_breath_by_breath_data(&expert_results);
```

RETURN VALUE:

-1 when a fatal error occurs, 1 when one or more non-fatal internal errors occur, otherwise 0.

APPENDIX 4: TECHNICAL DATA PROTOTYPE II

1. Hardware

- Computer : IBM AT compatible, 8 MHz, coprocessor installed
- Monitor : EGA or VGA High Resolution Graphics Monitor
- AD-board : Data Translation 2811
- Anesthesia machine : Ohmeda Modulus II
- Ventilator : Ohmeda 7810 Mechanical Ventilator
- Flow signal calculated from : Ohmeda 5410 Volume Monitor
- Pressure signal from : Ohmeda 5500 Airway Pressure Monitor
- CO₂ signal from : Ohmeda 5200 CO₂ Monitor
- Fresh gas flow calculated from : Ohmeda 5410 Volume Monitor

2. Software

- Size of complete executable program : 118 kB (83 kB code, 35 kB data, stack, and others)
- Sampling frequency for real time signals: 20 Hz
- Program speed : 3 times as fast as real time, on the 8 Mhz computer
- Compiler : Microsoft C Optimizing Compiler, version 5.1
- Expert system tool : SIMPLEXYS Expert System Language

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